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A randomised controlled clinical trial to investigate the rates of alignment of the upper and lower labial segments, rates of extraction space closure in the upper and lower buccal segments and treatment efficiency using conventional, active and passive self-ligating orthodontic brackets

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**A RANDOMISED CONTROLLED CLINICAL TRIAL TO
INVESTIGATE THE RATES OF ALIGNMENT OF THE UPPER AND
LOWER LABIAL SEGMENTS, RATES OF EXTRACTION SPACE
CLOSURE IN THE UPPER AND LOWER BUCCAL SEGMENTS AND
TREATMENT EFFICIENCY USING CONVENTIONAL, ACTIVE AND
PASSIVE SELF-LIGATING ORTHODONTIC BRACKETS**

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BDS, MFDS RCSEng, MOrth RCSEng

**A dissertation submitted to the University of Bristol in accordance with the
requirements of the degree of Doctorate of Dental Surgery in Orthodontics
in the School of Oral and Dental Sciences, Faculty of Medicine and
Dentistry**

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Abstract

This study is composed of three parts. The principal aim was to compare the rate of alignment of the upper and lower labial segments using conventional Omni, active In-Ovation R and passive Damon 3MX self-ligating brackets. The second part of this study was to investigate the rate of extraction space closure in the buccal segments for all subjects. The third and final element of this study was to investigate the efficiency of treatment for all three bracket types.

100 eligible subjects undergoing upper and lower fixed appliance treatment with the loss of four premolars were randomly allocated to one of three treatment groups: conventional (Omni) $n=20$, active (In-Ovation R) $n=38$ or passive (Damon 3MX) $n=42$ self-ligating brackets. Study models were taken for all subjects at the start and at twelve week intervals until completion of treatment. The same archwire sequence was used in each case. The labial segment alignment of each study model was measured using a digital Vernier calliper and Little's Index of Irregularity. Once alignment was achieved, space closure was carried out using 150g NiTi coil springs and once again measured using a digital calliper.

Analysis of data using linear mixed models demonstrated a significant effect of bracket type on the rate of alignment in the mandible ($p=0.026$), but not the maxilla ($p=0.277$). In the mandible, rate of alignment was significantly greater with conventional brackets (Omni). There was no significant difference between the two self-ligating brackets.

The rate of space closure was significantly faster in males when compared with females for both the In-Ovation R ($p=0.001$) and the Omni brackets ($p=0.003$). This was also found to be the case for Damon 3MX brackets although this was not shown to be statistically significant.

The results demonstrated a significant difference between the conventional and the two self-ligating brackets in relation to the total chair side treatment time, with the Omni bracket subjects total treatment time taking on average 50 minutes longer. They also showed a significant difference in the total number of appointments between the In-Ovation R and the Omni bracket ($p=0.0009$), with the In-Ovation R requiring fewer appointments. In all other analyses there were no significant differences.

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I would like to dedicate this thesis to my late father Basharat A. Butt.

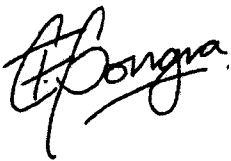
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Author's Declaration

I declare that the work within this dissertation was carried out in accordance with the Regulations of the University of Bristol. The work is original, except where indicated by special reference in the text, and no part of the dissertation has been submitted for any other academic award.

Any views expressed in the dissertation are those of the author and in no way represent those of the University of Bristol.

The dissertation has not been presented to any other University for examination either in the United Kingdom or overseas.

A handwritten signature in black ink, appearing to read 'G. Songra' with a stylized flourish at the end.

Goldie T B Songra

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1 Review of the Literature

1.1 Introduction

The human race has been fascinated with moving teeth for a very long time, with some form of 'orthodontics' and tooth movement having been practised for centuries (Weinberger 1934). For example, Ancient Egyptian mummies have been discovered with metal bands wrapped around individual teeth and with catgut used to close spaces (Paladin 2005). Both Hippocrates and Aristotle contemplated the various dental conditions and ways to straighten teeth, as far back as 400 to 500 BC. However, it was not until Roman times and Aurelius Cornelius Celsus that the first orthodontic treatment plan was recorded, where digit pressure was noted as being able to guide an aberrantly erupting tooth into its correct position (Wahl 2005a).

1.2 History of Orthodontic Appliances

The practice of fixed orthodontic appliances can be traced back as early as the 18th Century. Pierre Fauchard published his book "The Surgeon Dentist" in 1728 with a whole chapter dedicated to methods used to straighten teeth (Wahl 2005a). Fauchard is also credited with the development of the 'bandeau'. This was a horseshoe shaped piece of precious metal for the maxilla to which teeth were ligated. This was the first expansion appliance and was to go onto influence, inspire and ignite modern mans' desire to have straight teeth.

It was not until the late 19th Century that Edward Angle, regarded by many as the father of modern orthodontics, developed his E or expansion-arch, where a partially threaded wire was attached to banded molar teeth (Angle 1907).

During use the wire was lengthened by the advancement of a nut on the threaded portion of the wire. Since the teeth were only ligated to the expansion arch the tooth movement achieved was tipping (Angle 1907).

The E-arch was then followed by Angle's Pin and Tube appliance (Angle 1916). This appliance was designed to overcome some of the problems associated with the original E-arch, allowing all of the teeth to be banded using a tube soldered to the labial surfaces. The archwire was constructed with corresponding soldered pins which would engage the tubes and therefore allow more controlled tooth movement. There was however a major drawback

in the use of this appliance, as the soldered pins required repositioning every time the teeth moved. Consequently it was not a popular appliance and only Angle and one of his students ever mastered its clinical use (Proffit 2007).

Nevertheless the era of modern orthodontics had begun and soon a more advanced appliance, the 'Ribbon Arch', was introduced by Angle (Angle 1920). This was a modification of the earlier pin and tube appliance which overcame the problem of resoldering new pins onto the archwire, or making a new appliance every time the teeth had moved. It did so by allowing a 0.010" x 0.020" sized ribbon of gold wire to be placed in a vertical slot that was cut behind the tube on each band. The wire could then be held in place by pins. Although easier to use than the Pin and Tube, this appliance still only resulted in partial alignment of the teeth due to considerable movement of the archwire within the band slot or 'slop'. Root torquing was not particularly efficient and additional adjustments to the wire would need to be performed by the operator, despite the use of what was a rectangular cross-sectional arch wire (Proffit 2007).

The next significant step in the development of orthodontic appliances and techniques was the introduction by Angle of the Edgewise appliance (Angle 1928). This appliance was capable of allowing three dimensional control of tooth position, overcoming many of the shortcomings of the ribbon arch appliance. Angle also made additional modifications to this new appliance. He changed the dimensions of the slot to 0.022" x 0.028" and re-orientated the slot position from the vertical to the horizontal. This allowed the wire to be rotated by 90 degrees and inserted 'Edgewise' into the newly positioned horizontal slot. The Edgewise appliance allowed the clinician for the first time to have a positive three dimensional control over the position of the teeth. Different archwires could be used to carry out different movements. Initially a round wire could be used to allow tipping of the crowns of the teeth in the buccal/ labial direction and achieve initial alignment. This was then followed by a rectangular wire which would allow the torquing of the roots of the teeth in the buccal/ labial direction. The Edgewise appliance then relied on the clinician undertaking the final detailing of positioning of the teeth by placing specific bends in the wire to provide the individual in/ out, tip and torque for each tooth, *i.e.* three-dimensional position of each tooth. This was necessary as each bracket was of a universal standard design and, as such, was not specific or capable of individual tooth positioning (Thurrow 1973).

Angle advocated the expansion of the dental arches to relieve crowding rather than extraction of teeth (Wahl 2005b). One of Angle's students was Raymond Begg. Begg returned to his native Australia after learning the Angle technique, and after a period of research examining the indigenous population, concluded that extractions were often necessary. Subsequently he developed his own bracket in 1933 and then his own appliance based on Angle's ribbon arch appliance, namely the Begg appliance in 1965 (Wahl 2005b). This appliance was different to Angle's ribbon arch in three main ways:

1. A high strength single 0.016" stainless steel wire replaced the precious metal ribbon arch.
2. Inverting the bracket slot upside down so that the slot faced gingivally rather than occlusally.
3. The addition of auxiliary springs to control root position, *i.e.* torque.

Begg's new appliance utilised the concept of differential tooth movement, which was a low friction means of crown tipping, followed by root uprighting and allowed for the correction and closure of extraction spaces (Wahl 2005b).

The Edgewise and Begg appliances dominated the orthodontic world for the next 35 years and formed the bastion of fixed appliance treatment. That was until 1965 when Larry Andrews developed the Straight Wire[®] appliance. This was introduced onto the market a few years later and soon became widely accepted (Andrews 1972). This revolutionary new appliance was the first of what would be known as the preadjusted edgewise system, and would form the foundation of modern orthodontic appliances.

Andrews, in developing this new appliance, had removed the requirement of all the first, second and third order bends needed in the original Edgewise appliance archwire. This was facilitated by incorporating the individual three dimensional 'prescription' for each tooth, in each tooth specific bracket. The Straight Wire[®] appliance was based on the investigation of the occlusions of 120 non-orthodontic subjects with normal occlusions. Andrews was able to assess these occlusions and from this develop his "six keys to normal occlusion" (Andrews 1972). Andrews felt these keys were critical if a normal occlusion was desired at the end of fixed orthodontic appliance treatment, and was found to be present in all of the 120 normal occlusion subjects.

The six keys were as follows:

1. **Molar relationship:** The distal surface of the distobuccal cusp of the upper first molar, should make contact and occlude with the mesial surface of the mesiobuccal cusp of the lower second molar.
2. **Crown Angulation:** The gingival portion of the long axis of each crown should be distal to the incisal portion, varying with the individual tooth type.
3. **Crown Inclination:** Anterior teeth- upper and lower crown inclination should be sufficient to resist overeruption of the anterior teeth. Upper posterior teeth- there should be constant lingual crown inclination from the canines to the second premolars with slightly more inclination in the molars. Lower posterior teeth- there should be a progressive increase in lingual crown inclination from the canines to the second molars.
4. **Rotations:** There should be no rotations.
5. **Spaces:** There should no spaces between the teeth.
6. **Occlusal Plane:** There should be a level plane of occlusion or a slight curve of Spee.

Since the introduction of the Straight Wire[®] appliance various bracket designs have been introduced to the orthodontic market with differing 'prescriptions' for each tooth. The rationale has been to allow specific treatment mechanics and/ or to achieve a better and more stable final position of the teeth at the end of treatment (Bennett & McLaughlin 1994).

The major advantage of the preadjusted Edgewise appliance, compared to the original Edgewise appliance, is the lack of adjustment required by the clinician, particularly a reduction in the need for chair side wire bending. In addition, the use of the 'straight archwire' has meant the principle of sliding mechanics could be more readily employed during treatment. This enabled teeth to be more easily moved bodily, or space closure to be carried out by moving teeth 'en masse' along the archwire (Bennett & McLaughlin 1994). This added to the popularity of the system. However, the major disadvantage of this appliance when compared with the more traditional Edgewise mechanics of closing loops, was the high level of friction between the slot and the wire. This can result in slower tooth movement and particularly a loss of anchorage during treatment (Kesling 1988).

To overcome this limitation, Peter Kesling and his team developed the Tip-Edge appliance (Kesling 1988). Tip-Edge utilised the Begg philosophy of free tipping followed by uprighting, and combined it with the improved finishing of the preadjusted Edgewise appliance. By using the Begg mechanics of differential tooth movements, only very light forces are needed to translate the teeth into their pre-finishing positions. The subsequent uprighting is achieved with the use of auxiliaries such as sidewinder springs, and finally large dimension rectangular wires in a rectangular slot.

Over the last century a large number of appliances, systems and philosophies have been introduced to treat malocclusion, each with their own advantages and disadvantages. Current modern orthodontic treatment aims to provide the most efficient, safe, reliable and beneficial treatment to the patient. It does so by utilising parts and/ or modifications of each of the appliances mentioned above.

1.3 Methods of Ligation

Whether clinicians prefer to use the Edgewise, Straight Wire[®], Begg or Tip-Edge appliances, a requirement in each case is that the archwire must be securely held within the bracket slot. Traditionally this was carried out using ligatures made of Stainless Steel, or brass pins in the case of the Begg appliance. These methods of ligation were cheap, robust and biologically inert. However, they were not without their weaknesses namely, the time required to tie in each archwire and the risk of trauma to the patient from the free ends (Shivapuja & Berger 1994).

Elastomeric modules were introduced in the late 1960's and even though they had their limitations, they were generally accepted by the whole profession because of their ease of use, and the speed of changing an archwire compared with the use of Stainless Steel ligatures (Eliades & Pandis 2009).

A number of disadvantages of elastomeric modules have been identified which include; microbial accumulation, archwires not seating fully during torquing or rotational movements and the occurrence of binding during sliding mechanics (Taloumis *et al.* 1997). A number of *in vitro* studies also found that the use of modules significantly increased friction and thus resistance to sliding (Edwards *et al.* 1995; Hain *et al.* 2003; Khambay *et al.* 2004, 2005). The

oral environment has also been found to have an adverse effect on elastomerics (Ash & Nikolai 1978; Iwasaki *et al.* 2003). Water absorption accelerates the force decay of elastomerics (Taloumis *et al.* 1997). Moisture uptake leads to a weakening of non covalent forces and then degradation of the material. This along with heat causes a decrease in the dimensional stability of the elastomeric, causing force to be lost in the first 24 hours by up to 50 to 70% (Huget *et al.* 1990; Taloumis *et al.* 1997).

Self-ligating brackets have more recently been introduced into clinical practise. This is due, in part, to the increased friction associated with ligation and also the potential infection control issues.

1.4 Self-Ligating Brackets

As the name suggests, self-ligating (SL) brackets do not require any external form of ligation *i.e.* Stainless Steel ligature or elastomeric module, but have an inbuilt ligation mechanism to hold the archwire in the slot. The self-ligating bracket is not a new development with the first such bracket, the Russell Lock attachment, described approximately 70 years ago by Stolzenburg (1935). It comprised a nut and bolt apparatus that was attached to a band. The archwire was held in place by the adjustable nut, which screwed into the labial surface of the slot. The flat lingual surface of the nut created a 'fourth' wall, and by varying the position of the nut one could control the interaction between the archwire and the bracket. It was reported that using the Russell attachment was considerably more comfortable for the patient, required shorter visits and that the overall treatment time was shorter than when using the conventional brackets of the day (Stolzenburg 1946). These benefits have been re-examined more recently by Maijer & Smith (1990) who also claim that SL brackets have improved aesthetics, are more comfortable, smoother and less traumatic. Further advantages of SL brackets have been reported to include; reduced friction, full and secure wire ligation, improved oral hygiene and anchorage conservation (Turnbull & Birnie 2007).

There are a number of SL brackets available with differing techniques for the secure ligation of the archwire (Table 1).

Table 1 Chronology of the self-ligating bracket (Harradine & Birnie 2010)

Bracket	Year of Development
Russell Lock	1935
Ormco EdgeLok	1972
Forestadent Mobil-Lock	1980
Orec Speed	1980
“A” Company Activa	1986
Adenta Time	1994
“A” Company Damon SL	1996
Ormco TwinLock	1998
Ormco/ “A” Company Damon 2	2000
GAC In-Ovation	2000
Gestenco Oyster	2001
GAC In-Ovation R	2002
Adenta Evolution LT	2002
Ultradent Opal	2004
SDS Ormco Damon 3	2004
3M Unitek SmartClip	2004
SDS Ormco Damon 3MX	2005
Class One Carriere SLB	2005
GAC In-Ovation C	2006
Forestadent Quick	2006

Lancer Praxis Glide	2006
Ultradent Opal Metal	2006
3M Unitek Clarity SL	2007
American Orthodontics T3	2007
Dentaurum Discovery SLB	2007
GAC In-Ovation L	2008
Ortho Technology Lotus	2008
Ormco Damon Q	2009
Ormco Damon Clear Aesthetic	2010

The Damon 3MX and the In-Ovation R brackets are two contemporary examples of a SL bracket which have recently gained in popularity within the orthodontic community.

1.4.1 History of the Damon Bracket

The original Damon SL bracket was introduced in 1996 by “A” Company and superseded the Activa bracket (Damon 1998a, b). The Damon SL had a slide that was capable of moving in a vertical direction on an otherwise conventional bracket, and so converted the twin tie-wing Siamese bracket into a tube or passive self-ligating bracket. The slide also acts as a fourth wall when in the closed position. Beneath the slide and within the bracket face, a U-shaped wire spring provided a positive open and closed position via a system of indents within the slide base. Unfortunately, these original brackets suffered from a major problem which was quantified in a study by Harradine (2001). This study consisted of 25 consecutive cases that had been in treatment for more than a year. Harradine found that 31 slides fractured and 11 had inadvertently opened between visits. This was thought to be due to work hardening of the metal slide.

The Damon 2 bracket was launched in 2000 by Ormco/ “A” Company and was re-engineered to address the problems of the original Damon SL bracket. This new bracket still retained the vertical slide which acted as a fourth wall for the arch wire slot, along with the U-shaped

spring to control its opening and closing. The slide was now housed within the shelter of the twin tie wings and this, in combination with metal injection moulding manufacture used to generate closer tolerances, virtually eliminated any accidental slide opening or breakage. An unfortunate side effect however, was that this also made the brackets more difficult to open and close (Harradine 2003).

The next stage in the evolutionary process was the Damon 3 bracket, released in 2004. Like the Damon 2 bracket the slide was housed within the tie wings. Similar to its predecessors, it allowed an unrestricted view of the archwire slot in both arches as the slide opened in a downwards direction, but the new bracket design had a small hole incorporated into the surface of the slide to permit access to the opening mechanism. A special tool could then be used to depress the Stainless Steel catch and open the slide in one continuous motion. Unlike its predecessor, the Damon 3 slide could be closed using light finger pressure and did not require the use of any special instruments. These new brackets were also semi aesthetic as the bracket base and half of the tie wings were made of a composite material. However, this led to significant problems including a high rate of bond failures, separation of the metal from the composite base and fracture of the composite tie wings (Eliades & Pandis 2009). To eliminate these problems, in 2005 Ormco launched the all new and all metal Damon 3MX bracket (Figure 1). This was similar to the Damon 3 bracket except that it was made completely from injection moulded Stainless Steel. The Damon 3MX has been recently superseded by the Damon Q bracket which is similar in many respects to the previous bracket design, but differs in the mode of the slide opening mechanism. The Q bracket has a new slide design and a special slide opening tool that requires a twisting action rather than a downward force, transferring reciprocal forces to the bracket rather than the tooth.



Figure 1 Damon 3MX brackets in open and closed positions

1.4.2 History of In-Ovation R Bracket

The In-Ovation bracket was introduced by GAC International in 2000.

The design and concept of the In-Ovation bracket is very similar to that of the original Speed bracket invented by Herbert Hanson in 1975 (Hanson 1980). Hanson combined his own concept of a dynamic and self-ligating appliance, with Angle's edgewise appliance resulting in the so called 'active' self-ligating bracket. The 'active' component was due to a spring loaded, self adjusting ligature-less design, which actively influenced the control of the archwire within the archwire slot (Hanson 1980). It featured a curved flexible spring clip made from a highly resilient super-elastic Nickel-Titanium that wrapped occlusally-lingivally around a miniaturised bracket body. The labial arm of the spring clip formed a fourth and flexible outer wall of the archwire slot (Graber *et al.* 2005).

The In-Ovation bracket possesses an active spring clip similar to the Speed bracket, which pushes the archwire into the base of the bracket slot once it is above a certain dimension. The principal difference between the In-Ovation and the Speed bracket is in the clip which is constructed from Cobalt Chromium alloy. Other differences include its twin configuration and the presence of tie wings. The spring clip once closed converts the arch wire slot into a rhomboid shape rather than a traditional rectangular shape tube, causing it to become

interactive with archwires above 0.018". This allows torque control and expression of the bracket prescription (Graber *et al.* 2005).

The In-Ovation R bracket was introduced in 2002. (Figure 2) The principal difference between the two versions being the reduced mesio-distal width of the anterior brackets in the "R" series, with the "R" standing for 'reduced', and therefore allowing for a greater inter-bracket span.

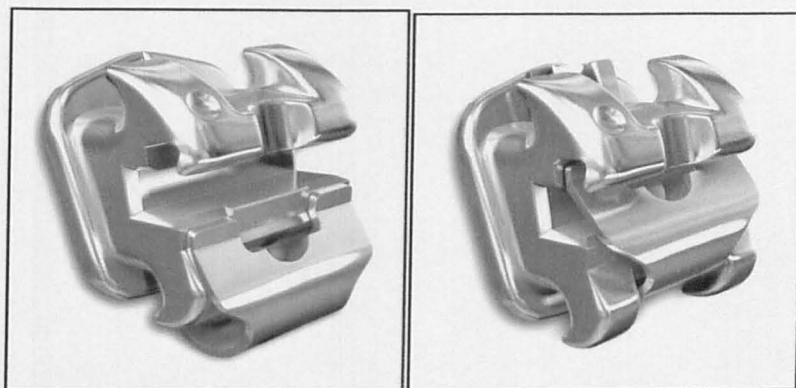


Figure 2 In-Ovation R brackets in open and closed positions

The spring clip is opened in a gingivally-occlusal direction. In the upper arch this is in a downward motion whereas in the lower arch is in an upward direction. It can be opened with gentle force using any instrument with a sharp edge, however this carries a risk of debonding the bracket if you inadvertently catch the bracket base rather than the latch. Therefore GAC manufactured the 'R' tool which looks like a periodontal probe with a ball on the tip. This allows the operator to slide to the edge of the bracket pad and then slip onto the latch which allows the clip to pop open. The other end of the instrument has a double ligature direction design and can be used to seat the wire into the bracket slot. The two prongs of the instrument are slightly wider than the widest In-Ovation bracket (Graber *et al.* 2005). Similar to the Damon 3MX slide, light finger pressure can be applied to close the spring clip.

Even though these brackets have been described as robust (Harradine 2003), some disadvantages have been reported. Visualisation of the gingival end of the spring clip can be difficult, especially in the lower arch. Also excess composite at the gingival aspect of the bracket can be difficult to see, and if not removed before setting may hinder access to the

spring clip opening latch. The spring clip can also inadvertently close before the archwire has been placed into position.

A common problem found with both the Damon SL and the In-Ovation SL brackets is the build up of calculus, which can result in the slide and spring clip opening mechanisms being difficult to access and open. A modification was introduced to the In-Ovation spring clip in 2006, where a channel was made at the point where the clip enters the slot blocker. The purpose of this hole is to allow clinicians to insert a probe and open the clip without accessing the 'whale's tail' at the gingival part of the bracket where the calculus is most likely to build up.

1.5 Active versus Passive

The major difference between the two designs of SL brackets is whether the brackets have active clips or passive slides. The In-Ovation R system is an active SL bracket whereas the Damon 3MX system is a passive SL bracket. Active spring clips physically invade the bracket slot from the labial side and have the potential to generate an additional force onto the archwire in a labio-lingual direction (Figure 3). Whereas the passive slides open and close vertically and essentially transform the SL bracket archwire slot into a tube, with no power to exert any additional force to the archwire. The potential advantages and disadvantages of each system have been the topic of considerable debate in recent years. (Sims *et al.* 1993; Matasa 1996; Read-Ward *et al.* 1997)

Active spring clips reduce the archwire slot depth from 0.028" to approximately 0.018", and will therefore only become active once an archwire of dimension greater than 0.018" is inserted into the slot (Figure 3). However, an active clip can also generate additional force from the archwire, independent of its size, when a tooth or part of it is rotated or is lingually displaced. As the spring clip does not reduce the slot dimension in a uniform manner, *i.e.* it encroaches more into the gingival rather than the occlusal part of the slot, the active force from the clip is also dependent on the vertical position of the archwire within the slot.



Figure 3 Side view of In-Ovation R bracket

An archwire greater than 0.018" in size will have a continuous lingually directed force applied to it by the spring clip, which will force the wire further into the base of the slot. This feature has led many to speculate that active SL brackets are much more effective at expressing their torque and from an earlier treatment stage (Graber *et al.* 2005). A study by Badawi *et al.* (2008) demonstrated that the lingual force derived from the active clip did indeed contribute to the reduction of the 'slop' of the archwire within the slot by 7 degrees and therefore influenced 3rd order tooth position.

The potential disadvantage of having an active force pushing down on the archwire is that an active SL bracket can mimic a conventional bracket tied with a Stainless Steel ligature or an elastomeric module, and can introduce additional friction compared to a passive SL bracket. This may be undesirable if 'sliding mechanics' are to be used. Laboratory studies carried out by Thorstenson & Kusy (2002) confirmed this hypothesis and demonstrated that active SL brackets generate more friction than passive SL brackets, and in some cases frictional forces were found to be 50 times greater with the active brackets. These results may need to be treated with caution, as laboratory findings do not necessarily translate to the clinical environment (Turpin 2009).

1.6 Friction

Friction is defined as “A force that retards or resists the relative motion of two objects in contact, and its direction is tangential to the common boundary of the two surfaces in contact” (Drescher *et al.* 1989).

The frictional force (FR) between the objects is directly proportional to the force (F) with which the objects are pushed together and the coefficient of friction (μ) which is a constant and depends exclusively on the objects in contact and their roughness, texture and hardness (Besancon 1985). Therefore:

$$FR = \mu \times F$$

There are two different types of frictional forces to consider. Static friction, which is the smallest amount of force required to initiate sliding between two objects that were previously at rest, and kinetic friction which is the amount of force that resists the sliding motion of the two objects over each other at a constant speed (Omana *et al.* 1992a). In clinical orthodontics, static friction is much more important, as teeth do not necessarily slide along the archwire (kinetic), but instead may ‘walk’ along with a combination of tipping and uprighting movements. Hence the force needed to overcome the initial static force is probably more relevant to tooth movement. (Omana *et al.* 1992b)

Friction can also affect the net amount of force being delivered to the tooth via the active components of the appliance. This is because the active forces have to first overcome the static friction, and only then can any remaining force be utilised to affect tooth movement. The applied force lost due to friction ranges between 12% and 60% (Kusy & Whitley 1997).

Resistance to sliding (RS) is another common term used when discussing tooth movement and this can be described as $RS = \text{Friction} + \text{Binding} + \text{Notching}$ (Kusy & Whitley 1997). When the archwire first contacts and binds against the edges of the bracket slot, the angle at which this occurs is called the critical contact angle (Kusy & Whitley 1999). As this angle between the archwire and bracket increases, it may lead to deformation of the wire and potentially notching which will further increase the resistance to sliding (Articolo *et al.* 2000).

1.6.1 Clinical implications of friction

1.6.1.1 Factors influencing resistance to sliding

A number of individual factors can affect friction, binding and notching in the clinical environment and in turn the rate of tooth movement, and these are listed below:

- Masticatory Forces
- Angulation of Archwire
- Size of Bracket
- Size of Archwire
- Effect of Lubrication
- Archwire Material
- Bracket Material
- Method of Ligation

Reviewing these in turn:

1.6.1.1.1 Masticatory Forces

Frictional resistance has been primarily studied *in vitro* (Braun *et al.* 1999), whereas the clinical situation that it is trying to represent or mimic can be very different. Different factors have been shown to reduce friction at the bracket and archwire interface by 85% (Liew 1993). These phenomena include chewing, speaking, swallowing and food particles in contact with the fixed appliance and all periodic and repetitive motions which cause minute movements of the teeth and the orthodontic appliance. These vibrations or oscillations in the system can momentarily decrease the surface contacts, which provide an associated instantaneous elimination of the normal force. Braun *et al.* (1999) carried out experiments *in vitro*, which showed that vibrations caused frictional resistance to momentarily fall to zero in 95.8% of cases. Whilst a number of authors have shown *in vitro* that masticatory forces consistently and predictably reduce friction (Frank & Nikolai 1980; Huffman & Way 1983; Kapila *et al.* 1990; Yamaguchi *et al.* 1996; Braun *et al.* 1999), some authors have not taken into account the force of ligation as a factor (Ziedenisberg 1997). Whereas others have shown that there is no difference to friction with mastication, and an *in vivo* study carried out by Iwasaki *et al.* (2003) showed that it does not eliminate friction associated with sliding mechanics.

It has therefore been suggested that *in vitro* vibration simulation of an *in vivo* occlusal and masticatory force can lack validity (Harradine 2003).

1.6.1.1.2 Angulation of Archwire

It has been shown by a number of workers that the greater the angulation, *i.e.* critical contact angle between the archwire and the bracket, the greater the friction and hence resistance to sliding (Andreasen & Quevedo 1970; Articolo *et al.* 2000; Redlich *et al.* 2003; Moore *et al.* 2004). The effect of binding and notching due to the critical contact angle of each bracket and archwire has been tested by many authors. At a zero degree angulation or when angulation was not taken into account, then SL brackets demonstrated lower friction than conventional brackets (Sims *et al.* 1993; Read-Ward *et al.* 1997). Although when tipped relative to the archwire, SL brackets demonstrated similar frictional forces to those observed with conventional brackets with both Stainless Steel ligatures and elastomeric modules (Bednar *et al.* 1991). This was later confirmed by Loftus *et al.* (1999) who showed that there was no difference in resistance to sliding with SL brackets when tipped.

A further multi bracket study found that inter-bracket distance was inversely proportional to resistance to sliding (Kusy & Whitley 2000). This suggests that as inter-bracket distance increases, the resistance to sliding decreases and *vice versa*. The main reason for this is probably due to the smaller critical contact angle between the archwire and the bracket slot in the case of wider brackets which in turn results in less binding or notching.

To summarise, studies carried out predominantly *in vitro*, have shown that if the arch is level and aligned then using SL brackets may result in lower friction and therefore resistance to sliding. However, this advantage is soon lost if the critical contact angle is reached, even for a SL bracket.

1.6.1.1.3 Size of Bracket

The overall size of the orthodontic bracket itself has also been investigated and its effect on friction. This has provided some conflicting results.

Tidy (1989) showed that friction was greatest for narrow brackets, as narrow brackets allow tipping movements (Drescher *et al.* 1989), and therefore increase the critical contact angle of the archwire relative to the bracket. In contrast, other studies have shown that friction is greatest with wider brackets (Frank 1979; Frank & Nikolai 1980), and speculated that not

only was the normal force on the archwire an important factor, but the contact area between the archwire and the bracket slot was a major feature in determining the frictional resistance.

1.6.1.1.4 Size of Archwire

A large number of investigations have concluded that an increase in archwire size, going from a round wire to a large rectangular wire increases the friction in the experiment (Andreasen & Quevedo 1970; Kapila *et al.* 1990; Loftus *et al.* 1999; Redlich *et al.* 2003; Moore *et al.* 2004). If bracket tip and critical contact angles are negligible then this effect can be explained by considering two different sizes of archwires. A round 0.016" wire in a rectangular 0.022" x 0.028" slot will have a large amount of 'slop' to move around within the bracket slot. Therefore, the archwire will not be subject to high frictional forces unless certain ligation methods are being used, which apply a normal force onto the wire hence seating it in the slot. Whereas contrast that with a second much larger 0.019" x 0.025" rectangular archwire being placed into the same slot, the amount of 'slop' has diminished significantly and therefore the resistance to sliding is much more likely with all types of bracket systems (Andreasen & Quevedo 1970; Frank & Nikolai 1980; Angolkar *et al.* 1990; Kapila *et al.* 1990; Loftus *et al.* 1999; Moore *et al.* 2004).

1.6.1.1.5 Effect of Lubrication

The role of saliva on friction is controversial as it has produced conflicting results (Stannard *et al.* 1986; Baker *et al.* 1987; Read-Ward *et al.* 1997). The different experimental methods used in the literature make it difficult to compare results directly (Hain *et al.* 2003). Baker *et al.* (1987) showed that saliva decreased friction, as it acted like a lubricant and aided the sliding of the archwire within the bracket slot. Other studies conversely demonstrated that saliva increased friction as it offers more resistance to sliding, and a greater amount of force is required to overcome the static friction between the archwire, saliva and bracket interface (Stannard *et al.* 1986; Angolkar *et al.* 1990; Pratten *et al.* 1990). Whilst Andreasen & Quevedo (1970) concluded that the effect of saliva is insignificant.

Looking at the effect of lubrication with specific materials, Edwards *et al.* (1995) showed that under wet conditions both Stainless Steel ligatures and elastomeric modules increased friction. Although Hain *et al.* (2003) found that friction was reduced when modules were lubricated with saliva. These contrasting results support the finding that there is little difference between dry samples and saliva samples (Andreasen & Quevedo 1970).

Kusy (1991) and Downing *et al.* (1995) have questioned the validity of experiments carried out using artificial saliva, as they suggested that artificial saliva is merely an alternative to, rather than a true and accurate substitute for human saliva.

1.6.1.1.6 Archwire Material

A review of the literature regarding archwire materials and friction once again demonstrates the conflicting nature of the many laboratory studies on the subject.

It has been suggested by a number of workers that Stainless Steel archwires show the least amount of friction (Drescher *et al.* 1989; Tidy 1989; Kapila *et al.* 1990; Kusy & Whitley 1990). However, Tselepis *et al.* (1994) have found that friction is greater with Stainless Steel archwires. Other studies have reported that Nitinol archwires produce the highest frictional forces (Omana *et al.* 1992; Karamouzos *et al.* 1997; Damon 1998a, b), or conversely the lowest (Peterson *et al.* 1982).

A hierarchy of archwire material and friction has been suggested by a number of researchers, who showed that friction was similar between Stainless Steel and Nitinol wires, which in both cases were less than that seen with Titanium Molybdenum Alloy (TMA) (Drescher *et al.* 1989; Angolkar *et al.* 1990; Kapila *et al.* 1990; Kusy & Whitley 1990; Kusy *et al.* 1991; Prosski *et al.* 1991; Articolo & Kusy 1999; Loftus *et al.* 1999).

When this hierarchy was investigated further it was felt that Nitinol and TMA wires gave rise to significantly greater frictional forces than Stainless Steel, with TMA resulting in higher frictional forces than Nitinol (Garner *et al.* 1986; Drescher *et al.* 1989; Tidy 1989; Bednar *et al.* 1991). Laboratory experiments carried out by Kusy and Whitley (1990) found that this was due to the surface of the TMA wire becoming cold-welded to the Stainless Steel of the bracket and adding to the resistance to sliding. Kusy and co-workers (1992) investigated this matter further, and found that if Nitrogen ions were implanted into the surface of the wire it would cause the archwire surface to harden and thereby decrease frictional force by as much as 70%. A randomised clinical trial conducted by Kula *et al.* (1998) used a split mouth design to determine whether space closure would be facilitated using an ion implanted TMA archwire. They concluded that there was no difference between the ion implanted TMA and the normal TMA archwire.

Ireland *et al.* (1991) suggested that sliding mechanics should be undertaken on a Stainless Steel archwire, rather than Nitinol wires if friction is to be minimised. Whereas some investigations have failed to detect a difference between archwire materials and friction (Omana *et al.* 1992b; Tselepis *et al.* 1994).

1.6.1.1.7 Bracket Material

The inter relationship between the bracket and archwire is also an important factor to consider and should not be overlooked when discussing friction. Materials with the same or similar coefficient of friction will demonstrate lower frictional forces when in contact, *i.e.* a Stainless Steel bracket, with a Stainless Steel wire, ligated with a Stainless Steel ligature, have a very favourable resistance to sliding. Whereas other materials have been shown to increase the friction in the system. Plastic and ceramic bracket materials have been shown on a number of occasions to demonstrate the highest levels of resistance to sliding (Angolkar *et al.* 1990; Pratten *et al.* 1990; Keith *et al.* 1993; Downing *et al.* 1994).

1.6.1.1.8 Method of Ligation

Traditionally the archwire has been ligated with Stainless Steel ligatures, which has been shown by Shivapuja and Berger (1994), to increase the amount of added friction to the system whilst moving teeth. Khambay *et al.* (2005) in contrast, were able to demonstrate that this form of ligation produced the lowest frictional force.

Riley *et al.* (1979) have claimed that elastomeric modules produce less friction than Stainless Steel ligatures. A divergent view was taken by Bednar *et al.* (1991), who reported that elastomeric modules cause more friction than Stainless Steel ligatures. However, a study by Matarese *et al.* (2008) concluded that there was no difference between elastomerics and Stainless Steel ligatures.

Friction has also been attributed to how tightly the Stainless Steel ligature is tied to the bracket whilst holding the archwire in place. Some studies have shown that loose Stainless Steel ligatures have less frictional resistance (Bednar *et al.* 1991; Taylor & Ison 1996; Hain *et al.* 2003), whilst some disagree showing no difference between tight and loose Stainless Steel ligatures (Iwasaki *et al.* 2003).

Although studies have shown conflicting results regarding the use of elastomerics and Stainless Steel ligatures, a number of investigators concur that tying an elastomeric module in

a figure of '8' increases the friction considerably compared to the normal 'O' ring shape (Sims *et al.* 1993; Edwards *et al.* 1995; Voudouris 1997).

The introduction of SL brackets has led to a number of *in vitro* studies which have compared this type of ligation with the more traditional methods. The majority of studies investigating ligation methods and friction found that SL brackets produced less friction than conventional brackets with elastomeric modules and Stainless Steel ligatures (Berger 1990; Bednar *et al.* 1991; Sims *et al.* 1993; Shivapuja & Berger 1994; Voudouris 1997; Thomas *et al.* 1998). More specifically, it has been demonstrated that passive SL brackets produce the least friction (Berger 1990; Sims *et al.* 1993; Shivapuja & Berger 1994; Taylor & Ison 1996; Pizzoni *et al.* 1998; Thomas *et al.* 1998; Khambay *et al.* 2004; Griffiths *et al.* 2005; Budd *et al.* 2008; Kim *et al.* 2008).

Investigators found and confirmed that active SL generated higher frictional forces in comparison to passive SL brackets. This ranged from five times greater (Franchi & Baccetti 2006) to approximately fifty times greater (Thorstenson & Kusy 2002) frictional resistance than passive SL brackets. This is in contrast to a study by Henao & Kusy (2004) which showed no difference between active and passive SL brackets as wire size increased or archwire clearance reduced. These studies are also in contrast to results which showed there was no difference between SL brackets and conventional brackets, either with elastomeric modules or Stainless Steel ligatures (Bednar *et al.* 1991; Shivapuja & Berger 1994; Loftus *et al.* 1999), although some only demonstrated this finding when looking at larger dimensions of archwires (Read-Ward *et al.* 1997).

In summary, the majority of the experiments, which were conducted *in vitro*, tell us that all of the traditional methods of ligating the archwire, including the use of active SL brackets have shown to increase the friction within the appliance. Only passive SL brackets have been shown to have reduced or negligible amounts of friction whilst securing the archwire within the bracket slot.

Overall and after considering all of the factors affecting friction, Thorstenson & Kusy (2001) found that the SL brackets allowed more of the applied force to be used for sliding, rather than overcoming friction and resistance to sliding when compared with conventional brackets. Although it is important to remember that this statement is based on *in vitro* laboratory studies and it is known that friction and the resultant effect on tooth movement is a

multifactorial combination of the bracket, archwire and ligature interface (Ireland *et al.* 1991).

In addition, *in vitro* studies can lack validity due to their inability to simulate biological responses, as well as the difficulty of mimicking the clinical situation in the laboratory (Rinchuse & Miles 2007). Therefore *in vitro* laboratory experiments assessing the clinical effects of friction are difficult to carry out and to compare with the real *in vivo* clinical situation.

1.7 Space Closure

Edward Angle was a 'non-extractionist' and believed in the philosophy of arch expansion to create space for the misaligned teeth. In contrast, people like Raymond Begg, Charles Tweed and their followers were 'extractionists' and felt that dental extractions were necessary to achieve a more stable occlusion at the end of treatment. Tweed was disappointed with the amount of relapse that cases suffered after being treated with the expansionist approach and therefore retreated 100 of his cases with extractions (Wahl 2005b). The results he achieved convinced not only him, but many other of his fellow orthodontists that extractions were an acceptable and essential approach to treatment in many instances. This debate is still continuing today with various treatment philosophies being based on arch preservation and non-extraction treatment plans, whilst others advocate the use of extractions as part of their treatment regime. The pendulum of opinion within the orthodontic community continues to swing from either standpoint and is one of many 'controversies' within our profession (Proffit 2007).

If extractions are carried out to alleviate dental crowding, then at some point during orthodontic treatment space closure usually needs to be undertaken. This is due to the fact that few cases require the full space created by extractions for their treatment mechanics.

Space closure as part of the orthodontic treatment normally begins after the initial levelling and aligning phase is complete. There are many ways of closing spaces in orthodontics, when selecting an appropriate method it is important that consideration is given to some fundamental goals:

1. Differential space closure *i.e.* anterior retraction, posterior protraction or both
2. Minimum patient co-operation *e.g.* headgear or elastics
3. Axial inclination control
4. Control of rotations and arch width
5. Optimum biological response *e.g.* minimum tooth resorption
6. Operator convenience *i.e.* simple to use

(Burstone 1982)

Historically silk ligatures and elastic bands were used to close space. However, more recently there have been two major ways to close spaces in orthodontics, namely to use closing loops or to use the concept of sliding mechanics.

1.7.1 Closing Loops

These can either be incorporated into the continuous archwire itself or a section of archwire (Burstone & Koenig 1976) and provide an intramaxillary force (Brown 1984). Friction is eliminated because the teeth ligated to the wire stay in the same position on the wire. As the activated loop automatically tries to revert to its passive position the teeth move with, rather than along the wire. A wide range of different closing loops or springs can be incorporated into the archwire. Their specific design features can affect the forces that they produced, *i.e.* reduction in the cross section of wire, increasing the height of the loop, the strategic placement of helices and the placement of the loop closer to one tooth than the other to increase the range of activation. These are just a few of the many subtle differences that can be incorporated whilst carrying out space closure (Burstone & Koenig 1976; Burstone 1982).

In the past sectional arches were also popular when closing buccal extraction spaces, with a variety of different closing loop designs being available. These were again thought to be 'friction-less' systems (Burstone & Koenig 1976) providing closure of the remaining unwanted space effectively and efficiently. However, using the closing loop technique increased the amount of wire bending required and often resulted in the application of superfluous high forces (Bennett & McLaughlin 1994) with unwanted effects on the anchor teeth.

1.7.2 Sliding Mechanics

Unlike the Edgewise system, the preferred method of space closure using the preadjusted Straight Wire[®] system was to use the principle of sliding mechanics, ideally on a 0.019" x 0.025" dimension Stainless Steel archwire (Bennett & McLaughlin 1994; Damon 1998b). This technique according to its advocates offered the clinician the opportunity of minimal wire bending along with the added benefits of easier treatment, better efficiency and a higher quality of finish compared to using the standard Edgewise or Begg systems (Bennett & McLaughlin 1994).

Sliding mechanics uses the ability to move each individual tooth or a group of teeth 'en masse' if required and slide it along the archwire (Bennett & McLaughlin 1994). The biggest benefit of using this technique compared to the use of closing loops is the minimal wire bending required. It can be carried out in a number of different ways, a few of the most popular methods of force delivery are featured below:

- Elastomeric Powerchain
- Active Ligatures
- Elastics
- Coil Springs

1.7.2.1 Elastomeric Powerchain

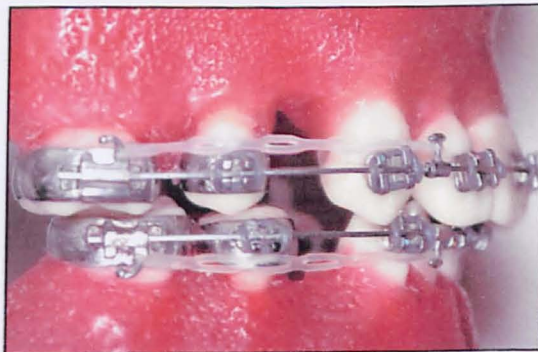


Figure 4 Elastomeric powerchain being used in buccal space closure

The synthetic elastomeric chain (powerchain) was introduced to the orthodontic market in the 1960's (Andreasen & Bishara 1970). Elastomeric powerchain is a polyurethane, a high

weight polymer which is predominantly bonded by covalent bonds. Polyurethane is a generic name that is given to elastic polymers that contain the urethane linkage. Polyurethanes are not direct polymers of urethane, but are synthesised through a process of reactions to produce a complex structure with a urethane linkage (Young & Sandrik 1979).

The advantages of an elastomeric powerchain are the same as those of an elastomeric module. This is because in essence the powerchain is made from a number of modules joined together at varied intervals. These advantages include quick application, patient comfort and availability in a variety of colours (Taloumis *et al.* 1997). Their disadvantages include microbial accumulation (Forsberg *et al.* 1991) and water absorption, which in combination can lead to a weakening of the non-covalent forces and polymer degradation (Huget *et al.* 1990). There is certainly a rapid loss of force within the first 24 hours after placement (Taloumis *et al.* 1997).

1.7.2.2 Active Ligatures

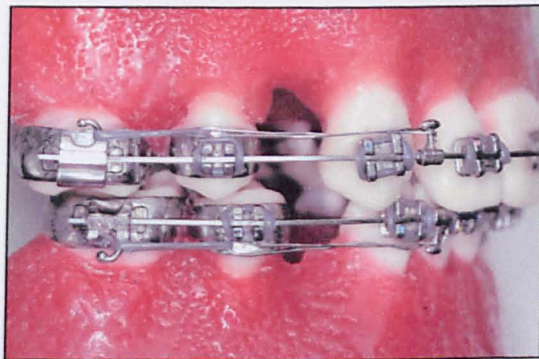


Figure 5 Active ligatures being used for buccal space closure

These are stretched elastomeric modules combined with a ligature wire (Bennett & McLaughlin 1994). They work by using the properties of the elastomeric module to move the teeth. As the material is stretched, some of the covalent bonds break and the polymer chains unfold. Once the stress is removed, the polymer should return to its original shape, provided the primary bonds within the molecular chains remain intact. However, if these bonds are broken, the elastomer's elastic limit will have been exceeded and permanent deformation will occur.

The advantages of active ligatures include low cost and ease of use. Disadvantages include the fact that it can be difficult to accurately determine the amount of force being applied and like other elastomers they lose a large amount of their force during their use (Andreasen & Bishara 1970; Killiany & Duplesis 1985; Nattrass *et al.* 1998), particularly in the first 24 hours in the oral environment (Huget *et al.* 1990; Taloumis *et al.* 1997).

1.7.2.3 Patient applied Intra- and Inter-arch Elastics

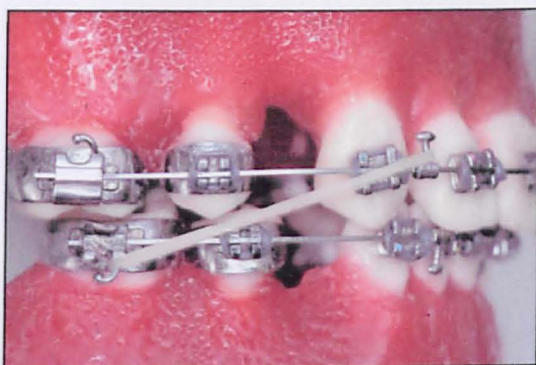


Figure 6 Patient applied Class 2 elastics being used in the buccal segments

Historically these have been employed since the late 19th Century and were pioneered by Calvin Case and H. A. Baker (Eliades & Pandis 2009). They are used with the Begg or Tip-Edge systems but can also be used with conventional preadjusted bracket systems. They work by moving blocks of teeth and also affecting their tip and torque.

They were initially made from natural rubber, but modern elastics are made from a similar polyurethane material as used in modules and powerchain, and are available in a variety of different sizes, thicknesses and strengths.

Their advantages are similar to other elastomeric materials and include ease of use and cost. However, their disadvantages are also the same once again including water saturation and hysteresis loss leading to rapid force loss in the first 24 hours. Unlike the other elastomers so far mentioned these are replaced each day by the patient in order to overcome this limitation.

1.7.2.4 Coil Springs

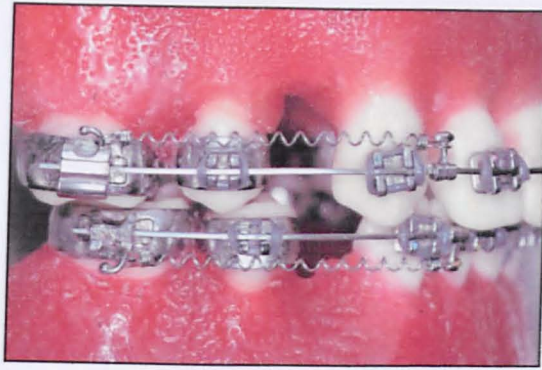


Figure 7 NiTi coil springs being used for buccal space closure

Coil springs can be divided into two groups namely, springs that have open coils and springs that have closed coils. They are usually found on a reel and are also available as individual springs in differing lengths with eyelets on either end. Open coils are activated by compression and normally push teeth apart and hence are used to create space. Whereas closed coils work under tension and are used to close spaces.

They can be made from a variety of different metals. Steel coil springs became available in the early 20th century (Anderson 1931) followed by Cobalt Chromium coil springs. The development of Nickel Titanium came in the 1980's from the Naval Ordnance Laboratories (Muir *et al.* 1986) hence the name NITINOL, an acronym of **nickel-titanium naval ordinance laboratory**.

Nitinol (NiTi) coils springs have been shown to retain more of their force over a given time period and provide a constant force compared to elastomeric modules and latex elastics (Muir *et al.* 1986; Angolkar *et al.* 1992). This was confirmed by both Samuels *et al.* (1993) and Dixon *et al.* (2002) who showed that closed coil (NiTi) springs have been found to be more consistent and more effective in carrying out space closure than active elastic modules. Another advantage is the lack of reaction with moisture in the oral cavity. They have also been shown to produce a light continuous force over a long range of action (Muir *et al.* 1986, 1988a, b). The 150g and 200g springs showed similar rates of space closure but produce a faster rate of space closure than a 100g spring (Samuels *et al.* 1998). It was also shown, once again, that NiTi coil springs are more effective than intra oral elastics (Sonis 1994).

Further research *in vivo* carried out by Nightingale and Jones (2003) compared NiTi coil springs with active ligatures and powerchain, and concluded by showing that there was no significant difference between the rates of space closure between the coil spring and powerchain. However, other studies have shown there was a difference between these two methods and the active ligatures (Samuels *et al.* 1993; Dixon *et al.* 2002). Even though NiTi springs gave the most rapid rate of space closure *in vivo*, Dixon *et al.* (2002) felt that powerchain provided a cheaper treatment option that was as effective, given that the main disadvantage of the coil spring is its expense. This topic is presently under investigation as a Cochrane review (Ye *et al.* 2009).

Currently a pack of intra oral elastics can be purchased for £0.57 plus VAT, compared to one metre of elastomeric powerchain which costs £6.91 plus VAT. Whereas a single coil spring with eyelets is supplied at £2.15 plus VAT (Personal Communication).

Since their development, all of the products mentioned above have been modified and refined to aid space closure and treatment mechanics.

Even though sliding mechanics was thought to improve the efficiency of treatment, occasionally over activation of the force delivery methods can cause a loss of tip and torque control on the incisors and molars (Bennett & McLaughlin 1994). This would obviously have to be corrected at the end of treatment and would usually require adjustment in the finishing archwire.

1.7.3 Optimum Force for tooth movement

For sliding mechanics to occur and friction to be overcome, a force needs to be used to move the teeth. This leads to the question, what is the optimal force for tooth movement?

It has been suggested that the optimum force levels for orthodontic tooth movement should be just high enough to stimulate cellular activity, without completely occluding the blood vessels in the periodontal ligament (Proffit 2007). Therefore, as vascularity is critical to tooth movement, Proffit (2007) has suggested that light continuous forces produce the most efficient tooth movement, and that heavy forces should be avoided. In addition, the use of light forces can help to avoid patient discomfort and tissue damage (Rygh 1986) and to conserve anchorage (Storey & Smith 1952; Smith & Storey 1952).

A study carried out by Owman-Moll *et al.* (1995) showed that tooth movement with a continuous force was more effective when compared with an interrupted force after seven weeks. They also showed that there was no difference in the degree or severity of root resorption, which differs from the findings of Weiland (2003) who described increased resorption in teeth treated with continuous forces.

Levander *et al.* (1994) radiographically evaluated the effect of a treatment pause of 2 to 3 months on teeth in which external root resorption had been discovered after an initial treatment period of 6 months with fixed appliances. The amount of root resorption was significantly less in patients treated with a pause than in those treated without interruption. The interruption of the forces facilitated reorganisation of damaged periodontal tissue and reduced root shortening. Weiland (2003) compared the amount of root resorption when teeth were subjected to constant or dissipating forces. Constant force was induced by a superelastic wire for 12 weeks, whereas dissipating forces were induced by Stainless Steel wires that were activated every 4 weeks. The results showed that the resorption craters on the teeth receiving constant force were 140% greater than the teeth in the group with dissipating forces.

It has also been postulated that the optimal force for tooth movement is not the same for everyone and may actually differ for each tooth and for each individual (Noda 2007; Proffit 2007).

It was originally suggested that 150g was an appropriate amount of force for space closure during sliding mechanics (McLaughlin & Bennett 1989). They also went on to suggest that a force of 100 to 150g is required bilaterally to retract the upper labial segment during overjet reduction (Bennett & McLaughlin 1992). Bennett and McLaughlin (1994) later found that active ligatures that delivered 50 to 150g of force for space closure were ideal.

Quinn and Yoshikawa (1985) suggested a force of 100 to 200g as optimal for the retraction of canines. However, Proffit (2007) claimed that you need at least 200g of force to slide a single canine tooth along an archwire, with 100g needed just to overcome the friction.

A study comparing a 150g spring with a 200g spring found no clinical difference in the rate of space closure (Samuels *et al.* 1998). While a systematic review on the subject concluded by showing that there was no strong evidence for the optimal force level for tooth movement (Ren *et al.* 2003).

1.8 Measuring Alignment

A number of methods of assessing alignment or crowding of the incisors have been proposed in the past (Little 1975).

Barrow and White (1952) described mandibular crowding in terms of fractions of permanent central incisor width. Mild mandibular crowding could be described as 'one third of a lower incisor' while 'four thirds of a lower incisor or more' would describe severe crowding.

Moorrees and Reed (1954) stated that crowding could be visualised as the numerical difference between mesiodistal crown width and the space available. However, this was an arch length assessment rather than a crowding index (Little 1975).

Another numerical method of assessing crowding was suggested using the amount of displacement and rotation of each incisor, adding up the cumulative scores (Van Kirk & Pennel 1959). For example, ideal alignment scored zero, less than 45° of incisor rotation or less than 1.5mm of incisor displacement scored 1, and greater than 45° of rotation or greater than 1.5mm of displacement scored 2. This was modified by Bjork *et al.* (1964) by using 15° as the division between normal and crowded incisors. They also assessed crowding by recording the incisors which were deviated from the 'midline of the alveolar process' by more than 2mm. Although these methods were numerical, they were not truly quantitative (Little 1975).

Crowding or 'labiolingual spread' has also been described as the deviation (measured in millimetres) of each incisor from the normal arch (Draker 1960). Another assessment of crowding involved the rating of severity on a scale of 0 to 5 (Proffit & Ackerman 1973). However, the subjective nature of both of these methods causes them to be lacking in accuracy and consistency, therefore a more reliable and truly quantitative method of assessing alignment or crowding was needed (Little 1975).

Little (1975) described his index as a quantitative method of assessing mandibular anterior irregularity. It measured the actual linear distance between adjacent anatomic contact points of the anterior labial segment. A score of zero would equate to perfect alignment measured from the mesial anatomic contact point of the left canine, to the mesial anatomic contact point of the right canine. Deviation from this would be as a result of displacement of the anatomic contact points of adjacent incisor teeth and the sum of these five measurements would

represent the relative anterior irregularity. A higher numerical index score represented greater displacements and therefore increased crowding.

Little (1975) obtained the five measurements directly from a cast of the arch rather than intraorally, as this allowed proper positioning and greater accuracy and consistency. The cast was viewed from above and each displacement was measured using callipers. He originally recommended using dial callipers as they were more accurate and easier to read to the nearest 0.1mm rather than Vernier callipers. However, the development of digital Vernier callipers which allow more accurate measurements to the nearest 0.01mm has meant that they have now replaced the use of dial callipers in the measurement of Little's Index of Irregularity.

This method does have some limitations. An arch can be assessed as having an Irregularity Index of zero as there may be no adjacent contact point displacements, however, the incisor teeth could be rotated in relation to the ideal archform and therefore assessed as not 'aligned'. The index also does not take into consideration any spacing or any vertical discrepancy between adjacent anatomic contact points if there is no labio-lingual displacement. Even with these limitations, Little's Index of Irregularity is still widely used and there have been no alternatives developed to improve the accuracy of the index (Clover 2008).

Numerous methods of measuring Little's Index of Irregularity have been reported in the literature. Some researchers have shown that it can be measured intraorally by the operator using digital callipers (Miles *et al.* 2006; Pandis *et al.* 2009), whereas most of the studies have recorded the scores directly from study models as described by Little himself (Almasoud & Bearn 2010).

However, other methods have also been suggested and can be divided into 2-dimensional or 3-dimensional methods. Two-dimensional methods include occlusal scanning of the study models with a flatbed scanner (Tran *et al.* 2003), photocopying the study models (Yen 1991), taking extra-oral photographs of study models or intra-oral photographs of patients' arches (Almasoud & Bearn 2010) and then either directly measuring or digitising the images.

It was felt that measurements using the 2-dimensional images would be easier to carry out, whilst eliminating the high potential of errors and variability associated with measuring directly from a 3-dimensional study model. It has also been shown that photocopying and scanning have good reliability and validity compared with measurements from study models (Tran *et al.* 2003).

However, this was contrary to the findings of Yen (1991) who showed that any significant deviation of the tooth from the perpendicular axis, such as severe tipping, or the angulation of the photograph could influence the accuracy of this method. The accuracy of these methods is also dependent on what is being measured. While arch width measurements have been shown to be similar, magnification produced by the photocopier of particular segments of an arch can affect arch length and space analysis assessment. This is caused by the study model being raised from the surface of the glass due to a curve of Spee. This along with other factors such as crowded tooth positions, differences in tooth inclinations and the convex surface of the teeth prevent accurate or reproducible measurements (Champagne 1992; Schirmer & Wiltshire 1997). This inability to accurately represent a 3-dimensional object as a 2-dimensional image limits the use of these methods for general observations, comparing pre- and post- treatment changes and individual tooth movements.

The range of 3-dimensional measurement methods include the reflex metrograph (Butcher & Stephens 1981; Takada *et al.* 1983), reflex microscope (West *et al.* 1995) and the 3-dimensional digitiser (Heiser *et al.* 2008).

O'Brien *et al.* (1990) investigated the efficiency of initial aligning archwires. They measured the 3-dimensional contact point displacement of the upper labial segment, and conducted error analyses to investigate the 3-dimensional plotting capabilities of the reflex metrograph. They found that measurements carried out on study models using the reflex metrograph were as accurate as the plaster models.

Similar error analysis was also carried out by West *et al.* (1995) who used a reflex microscope to digitise their study models. They also used Little's Index to measure alignment of the labial segments, and again found no statistically significant difference in measurement error in identifying points on the casts.

However these 3-dimensional methods are prone to errors because the distance between the contact points is recorded in both the horizontal and vertical planes, and so might not be a valid representation of Little's Index of Irregularity. They also rely on the availability of study models, produced from dental impressions (Almasuod & Bearn 2010).

To overcome this, the use of direct optical scanning of the mouth has been suggested to produce a 3-dimensional digital study model, which can then be used instead of the traditional plaster study cast for assessments, measurements, treatment planning and the

fabrication of orthodontic appliances and archwires. The most obvious advantage of digital study models as a substitute for plaster models is that they can be stored electronically, thus saving space. They also cannot degrade with repeated measurements, break, fracture or be damaged during storage, transportation and actual use (Tran *et al.* 2003). Digital study models also eliminate the time consuming procedures of fabrication, cataloguing, storage and retrieval that are associated with plaster study models (Ireland *et al.* 2008).

Current intra-oral optical scanning techniques can take up to 45 minutes per mouth and therefore in a busy orthodontic clinic do not offer a feasible alternative to an alginate impression. However, newer systems are currently being developed that are likely to substantially reduce the scanning time, making the routine acquisition of digital images rather than conventional impression taking a possibility (Ireland *et al.* 2008).

The use of a 3-dimensional laser scanner (Renishaw Cyclone Series 2) was investigated by a previous study into the accuracy of measuring Little's Index of Irregularity compared with digital Vernier callipers (Clover 2008). Two operators under similar conditions measured the contact point displacements on 25 sets of study models using digital Vernier callipers on two separate occasions, a week apart. The same 25 sets of study models were then scanned using the laser scanning machine, and the resulting 3D images were then measured by the same operators, again on two separate occasions one week apart under similar conditions. The mean intra- and inter-operator error was calculated for each measuring technique. It was found that the Vernier callipers proved to be more accurate than the laser scanner when used to measure labial segment irregularity (Clover 2008).

1.9 Measuring Space Closure

Studies investigating the rate of space closure in orthodontics have looked at a number of variables. These have ranged from bracket design (Lotzof *et al.* 1996), different ligation methods (Burrow 2010; Mezomo *et al.* 2011) and archwire properties (Huffman & Way 1983; Kula *et al.* 1998). However the variable that has been investigated most frequently is the method of force delivery (Sonis *et al.* 1986; Samuels *et al.* 1993; Sonis 1994, Samuels *et al.* 1998; Dixon *et al.* 2002; Nightingale & Jones 2003; Bokas & Woods 2006).

The methods used to measure the amount of space closure often differ between investigations. Traditionally researchers have taken lateral cephalograms and superimposed the pre and post space closure images, and measured between specific dental anatomical points (Dincer & Iscan 1994; Dincer *et al.* 2000; Thiruvengkatachari *et al.* 2006; Xu *et al.* 2010). Cha *et al.* (2007) found that the difficulty with this method was in identifying inherent landmarks and differentiating between the left and right hand sides of the patient, as well as evaluating 3-dimensional dental movements. Other drawbacks of serial cephalograms are tracing errors, high costs and the frequent exposure of the patient to radiation (Ghafari *et al.* 1998).

Some researchers have actually carried out their measurements intra-orally using digital callipers from the mesial aspect of the canine bracket to the distal aspect of the molar bracket (Miles 2007). Others have measured intra-orally using a flexible ruler and looking at the distance from the maxillary midline to the mesial of the canine, and measuring the amount of space opening between the two points to then calculate the rate of canine retraction (Burrow 2010). Both of these methods have to be questioned regarding their validity as they are prone to errors, they do not take into account bracket debonding failures and the inaccuracy of carrying out measurements intra-orally, with soft tissues potentially causing an obstruction.

To overcome this, Yee *et al.* (2009) carried out numerous measurements intra-orally but also measured study models. They measured from the bracket of the canine to the bracket of the molar, as well as the distance from the cusp tip of the canine to the mesiobuccal cusp of the first molar. They also took images of the study models using a flatbed scanner marked with reference points, and measured superimposed images to calculate the amount of canine retraction.

Study models appear to be the most popular method of measuring changes intra-orally and documenting malocclusion (Cha *et al.* 2007). These have been used to measure the distance between the canine cusp tip to the buccal groove of the first molar (Dixon *et al.* 2002; Nightingale & Jones 2003), or the distance between the distal contact point of the canine to the mesial contact point of the second premolar (Mezomo *et al.* 2011). It is important that points which are reproducible are used when repeated measurements need to be carried out. The use of the canine cusp tip needs to be evaluated, as it has been shown that cusp tips can be damaged and eroded during retraction (McGuinness 1992).

Study models also need to be stored and can be damaged, therefore alternatives to plaster models have been suggested. These include the use of photography (Schirmer & Wiltshire 1997), holographic technology (Ryden *et al.* 1982) and laser scanning to digitise the dental arch (Motohashi & Kuroda 1999).

Samuels *et al.* (1993) carried out measurements of study models using an x-y digitizer and looked at the distance between a point between the central incisors and a clear reproducible landmark on the first molar. They also used a reflex microscope and measured the study models once again using similar landmarks (Samuels *et al.* 1998).

3-dimensional computerised digital study models have been shown to be accurate and reproducible when measuring the amount of space closure compared to lateral cephalograms (Cha *et al.* 2007) and allow the researchers to measure not only distance moved but also rotations, vertical movement and arch changes (Cho *et al.* 2010). The disadvantages associated with digital models are the slow rate of data acquisition, difficulties in image projection and the high cost (Ireland *et al.* 2008).

Recent studies have shown that 3D digital models made using cone beam CT can be used as an alternative to conventional stone study models (Damstra *et al.* 2010; El-Zanaty *et al.* 2010). However, not only are patients subjected to radiation which may not be justified (Isaacson *et al.* 2008), but studies have also shown that using anatomic landmarks on the surface models were subject to identification errors in the segmentation process (Periago *et al.* 2008; Brown *et al.* 2009). CBCT also tends to underestimate the reference values and measurements and this ranges from 60.7% (Damstra *et al.* 2010) to 94.4% (Ballrick *et al.* 2008) when compared to direct digital calliper measurements (Lascala *et al.* 2004).

Therefore it can be said that either the use of direct measurements using study models, or the use of 3-dimensional digital study models using a range of image capture techniques, are the most popular methods of measuring orthodontic tooth movement and space closure.

1.10 Comparison of conventional and self-ligating brackets

1.10.1 Ligation, chair side time and efficiency

A number of *in vivo* studies have looked at and compared the treatment efficiency of using SL brackets compared to conventional brackets and have reported mixed results.

A study by Maijer and Smith (1990) showed that it was three times faster to use SL brackets than conventional brackets for the placement and removal of archwires. They also concluded that this resulted in a reduced chair side time of an average of seven minutes per patient. This could be used to schedule more patients, increase practice efficiency and improve patient-clinician relationships.

Shivapuja and Berger (1994) also showed a shorter treatment time and reduced chair time when using SL brackets compared to conventional brackets, due to a decrease in time taken for archwire placement and removal. They showed that the mean time taken to open and close a SL bracket was 41 seconds compared to tying and untying a conventional bracket with a metal ligature or a rubber ligature which took either 480 seconds or 140 seconds respectively.

This type of time saving was again shown by Berger and Byloff (2001). They compared four types of SL brackets with conventional brackets tied with Stainless Steel ligatures and elastomerics. Their study found that SL brackets saved on average 10 to 12 minutes per patient compared to tying Stainless Steel ligatures for both upper and lower arches. They also found that SL brackets saved 2 to 3 minutes per patient compared to elastomerics.

Turnbull and Birnie (2007) showed similar findings, however their time reduction was a little more modest at only 1.5 minutes per patient. The reduced friction generated by SL brackets has also been proposed as the reason for a reduction in treatment time (Hanson 1980; Berger 1994; Harradine & Birnie 1996; Damon 1998b).

It has also been suggested that the labour intensive, tedious and ergonomically unsatisfactory process of passing, placing and removing elastomeric modules is threatened with the ever growing popularity of SL brackets where a single operator can do everything (Turnbull & Birnie 2007).

Retrospective studies by Harradine (2001) and Eberting *et al.* (2001) both found that they had made significant time savings with patients who had been treated with SL appliances.

Harradine (2001) looked at patients treated with Damon SL brackets and compared them with patients treated with conventional brackets, with an equivalent level of occlusal irregularity as measured by the Peer Assessment Rating (Richmond *et al.* 1992). He found that there was a mean reduction of four months (from 23.5 to 19.4) in treatment time and four visits (from 16 to 12) during active treatment for the Damon group. He also found that there was an average time saving of 24 seconds in archwire removal and placement whilst using SL brackets per arch per patient. Even though attempts were made by the author to reduce bias by comparing similar patients, due to its retrospective nature it is not clear whether similar techniques were used as well as if all variables were controlled.

Eberting *et al.* (2001) again found that SL cases treated using Damon brackets had an average reduction of six months (from 31 to 25) and seven visits (from 28 to 21) when compared to conventional cases. Again it is not clear what treatment techniques were used or which variables were controlled. Another criticism of this study was that the selection criteria were not well detailed, and pre-treatment characteristics of the sample were not tested for equivalence (Ong *et al.* 2010). It is also pertinent to remember that retrospective studies can be potentially biased because there are many uncontrolled factors that could affect the outcome. These include greater experience, differing archwires, altered wire sequences, change in treatment mechanics, modified appointment intervals as well as observer bias (Miles *et al.* 2006).

More recently a large retrospective comparison of active SL brackets (Hamilton *et al.* 2008) as well as a prospective randomised clinical trial investigating passive SL brackets with conventional brackets (DiBiase *et al.* 2011) both reported that overall there was no reduction in treatment time, total number of visits or time spent in initial alignment.

1.10.2 Alignment

A number of other studies have also recently investigated the treatment efficiency of SL brackets compared to conventional brackets.

One of the first published studies which investigated this was by Miles (2005). This study compared a passive SL bracket (Smartclip) with conventional brackets in the mandibular arches of patients, either having undergone extractions or being treated on a non extraction basis, and measured the rate of initial reduction of crowding over the first twenty weeks. All patients were treated with identical wire sequences, which was an initial archwire of 0.014" NiTi followed by a 0.016" x 0.025" NiTi. Lower labial alignment was found to be better for the conventional brackets at ten weeks, however there was no difference between the bracket types at twenty weeks. Although this study had been reported as a clinical trial, there was no mention of sample size calculation, no blinding of measurement and no mention of standard deviations (Fleming & Johal 2010). Although it could be questioned whether it was appropriate to include patients requiring extractions, and comparing these to patients being treated on a non-extraction basis.

Miles *et al.* (2006) conducted another study which compared the rate of alignment of Damon 2 brackets with conventional brackets in the mandibles of patients using a split mouth design. In this study of 58 patients, one quadrant of the mandible was bonded with Damon 2 brackets and the other quadrant with conventional brackets and *vice versa*. Once again all of the patients had a similar archwire sequence and patients were recalled at 10 and 20 weeks. Labial alignment was measured using Little's Index of Irregularity and measured intra-orally using digital callipers. Contact point displacements of just three teeth were taken in each quadrant of the arch to represent the irregularity index for each bracket type. It was found that Damon 2 brackets were less effective at reducing irregularity at both 10 and 20 week intervals and that the conventional brackets achieved a 0.2mm reduction in irregularity than Damon 2 brackets. Although a statistically significant difference was found between the two brackets, once again not all of the patients were similar. The cohort were a mixture of either extraction or non extraction cases, there was no mention of sample size, standard deviations or blinding to measurements which can all lead to a higher risk of bias (Chen *et al.* 2010). The suitability of using a split mouth design to analyse irregularity and efficiency of alignment has also been questioned (Fleming *et al.* 2009), as having one half of the arch

ligated with elastomerics may have stopped the free sliding of the archwire through the Damon 2 brackets past the midline.

This was in contrast to a study again comparing Damon 2 brackets with conventional brackets (Pandis *et al.* 2007). All of the patients were treated on a non-extraction basis and only the mandibular arches were investigated. They found that there was a statistically significant difference in the rate of alignment for patients with moderate crowding *i.e.* Irregularity Index <5mm, as these patients completed alignment 2.7 times faster with SL brackets than compared to conventional brackets. Severe crowding *i.e.* Irregularity Index >5mm showed a similar but less powerful tendency as treatment time was 1.37 times faster with SL brackets but this was not significant. Overall, it was reported that there was no difference between the brackets in time required to alleviate mandibular crowding. These results need to be considered with caution though, as complete alleviation of crowding was not measured but in fact judged clinically by the operator which could be thought of as subjective and increasing the risk of bias, as well as the study actually using different archwire sequences for either bracket group. The Damon 2 patients had an initial archwire of 0.014" NiTi followed by a 0.014" x 0.025" NiTi, whereas the conventional bracket patients started with a 0.016" NiTi followed by a 0.020" Sentalloy archwire. The use of a thicker and rectangular archwire with the Damon 2 brackets could explain the quicker alignment rates, than compared to the round wires used with the conventional brackets.

More robust randomised controlled trials investigating passive SL brackets with conventional brackets have all concluded by showing that there was no difference in alleviating irregularity initially or overall (Scott *et al.* 2008; Fleming *et al.* 2009).

Fleming *et al.* (2009) analysed the 3-dimensional contact point displacement of the mandibular arch in non-extraction patients with mild crowding and looked at the whole arch from molar to molar rather than just the anterior labial segment. They also only looked at the first eight weeks. This study concluded by showing no difference between the two bracket types, however differences may only become apparent in cases with severe crowding. The other study looked at the mandibular labial segment of patients requiring premolar extractions and measured Little's Index until the placement of a 0.019" x 0.025" Stainless Steel archwire (Scott *et al.* 2008). Once again they concluded that the SL brackets were no more clinically effective than conventional brackets during the alignment phase of orthodontic treatment.

All of the studies so far had only investigated incisor irregularity in the mandibular arch, whereas Pandis *et al.* (2010) compared the time required to complete alignment of the maxillary anterior teeth. They compared a passive SL bracket (Damon 3MX) with an active SL bracket (In-Ovation R) in patients treated on a non-extraction basis. It was found that there was no difference between the two bracket systems. Even though initial irregularity was measured on study models using digital callipers, complete alignment was judged clinically by the operator without taking any further study models or measurements. The rate of alignment was measured by calculating the time taken in days. Another criticism of this randomised control trial was that it did not have a control group, *i.e.* a conventional bracket group with which they could compare the two SL brackets.

With all of these studies, one can surmise that a potential time saving with SL brackets is not during initial alignment, but could be at a later stage of treatment. Perhaps in extraction patients, the reduced normal force of friction with SL brackets allows faster sliding mechanics during space closure and therefore reduces treatment time (Miles 2007).

1.10.3 Space Closure

Studies investigating the rate of space closure have also reported no difference between SL brackets and conventional brackets (Miles 2007; Ong *et al.* 2010; Mezomo *et al.* 2011). Miles (2007) published the first study to evaluate the rate of *en-masse* space closure in extraction cases, comparing the SmartClip SL bracket with conventional brackets tied with Stainless Steel ligatures. A split mouth design was used on 13 patients, all having conventional brackets bonded anteriorly and with one side of the arch the premolar and molar teeth being bonded with the SL brackets, whilst the other side with the conventional brackets and *vice versa* on consecutive cases. Measurements were made intra-orally from the mesial of the canine bracket to the distal of the molar bracket and taken until one space in the arch had closed. The difference between the first and the final measurement was calculated and divided by the number of months to give the rate of space closure. It was found to be 1.1mm per month for the SmartClip and 1.2mm per month for the conventional bracket which was not statistically significant.

Although Miles (2007) did note that there was a time saving in ligating and untying the archwires *i.e.* chair time between the SL bracket and the conventional bracket. It can be

argued that this investigation's methodology was flawed in a number of ways. The method of measuring space closure does not take into account the difference in mesio-distal width of the SL and conventional brackets. There was a small sample with no sample size calculation and no blinding of measurement. It has also been argued that the use of a posted archwire during space closure could have meant that tooth movement on one side of the arch may not have been independent of the other (Fleming & Johal 2010).

Another study with a small sample of only 15 patients found that there was no difference in the rates of tooth movement between SmartClip SL and conventional brackets (Mezomo *et al.* 2011). Once again they used a split mouth design and compared the rate of canine retraction in the maxilla. Space closure was carried out on a 0.018" Stainless Steel archwire and measurements were only taken for a three month period and not until complete space closure. This result does not conclusively prove that there is no difference between the two bracket types, as there could have been differences which may only have been obvious after three months or been achieved with a larger sample size. A way to overcome this would have been to undertake a power calculation, which was not carried out in this study.

A study that did undertake a power calculation in order to consider their appropriate sample size was an investigation by Ong *et al.* (2010). This study compared Damon 3MX with conventional brackets and investigated the efficiency of anterior tooth alignment and the amount of passive space closure during the first 20 weeks of treatment. Over the investigative period, it was found that there was no difference in irregularity score reduction between the SL and conventional brackets. There was also no difference between the maxilla and mandible. In addition, over the 20 week period there was no difference found between the SL and conventional brackets in terms of passive extraction space closure, and again no difference was found between the maxilla and mandible. This is an interesting study, confirming what has been shown by a number of previous researchers. However, due to its retrospective nature it was not a randomised study sample, therefore there is a possibility of sampling bias. A prospective study with randomised or consecutive assignment is preferred (Miles 2009). The study only measured each patient until week 20 rather than until the end of treatment or complete alignment, which may not be long enough to show any significant differences between the different bracket types, as differences may only become apparent in cases after a longer time interval (Fleming *et al.* 2009).

To conclude, some retrospective research shows reduced treatment times and fewer appointments with the use of SL brackets. The other available research which is predominantly prospective and of a high level of evidence, has so far shown there to be no difference between treatment times, treatment efficiency, time taken for initial alignment and time taken for 'en-masse' space closure between SL and conventional brackets.

2 Aims

The aims of this investigation were:

1. To investigate the rates of initial alignment of the labial segments of the maxilla and mandible with Damon 3MX passive self-ligating brackets, In-Ovation R active self-ligating brackets and OMNI conventional brackets.
2. To investigate the rate of extraction space closure in the buccal segments of the maxilla and mandible with Damon 3MX passive self-ligating brackets, In-Ovation R active self-ligating brackets and OMNI conventional brackets.
3. To investigate the efficiency of treatment with Damon 3MX passive self-ligating brackets, In-Ovation R active self-ligating brackets and OMNI conventional brackets.

2.1 Null Hypotheses

The null hypotheses state that:

1. There is no difference between the rates of alignment of the labial segments of the maxilla and mandible with passive self-ligating, active self-ligating and conventional brackets.
2. There is no difference between the rates of extraction space closure in the buccal segments of the maxilla and mandible with passive self-ligating brackets, active self-ligating brackets and conventional brackets.
3. There is no difference in the efficiency of treatment with passive self-ligating brackets, active self-ligating brackets and conventional brackets.

3 Materials and Methods

3.1 Materials used in the clinical environment

- Information sheet for participant (Appendix 1)
- Information sheet for parent/ guardian (Appendix 2)
- Consent form (Appendix 3)
- Orthoprint alginate impression material (Zhermack, Rovigo, Italy)
- Plastic impression trays (Dentsply DeTrey Gmbh, Konstantz, Germany)
- Fix tray adhesive (Dentsply DeTrey Gmbh, Konstanz, Germany)
- Alginator 2 alginate mixer (Cadco, Utrecht, Holland)
- Safety glasses
- Elastomeric separators (Orthocare, Bradford, West Yorkshire, UK)
- Lip/ Cheek retractors
- Patient and assistant suction
- Disposable dappens pots
- Microbrushes (Microbrush Products, Co. Waterford, Ireland)
- 37% o-phosphoric acid (Hawley Russell Ltd, Potters Bar, UK)
- 3 way air and water syringes
- Sterile water
- Transbond TM XT light cure adhesive primer (3M Unitek, Dental Products Division, Monrovia, CA, USA)
- Transbond TM XT light cure orthodontic adhesive paste (3M Unitek, Dental Products Division, Monrovia, CA, USA)
- Litex 695C LED light curing gun (DentAmerica, City of Industry, CA, USA)
- Mini LED Ortho (Satelec, Merignac, France)
- Reverse action bracket holder
- GAC Omni conventional brackets 0.022" slot Roth prescription (GAC Orthodontics, Bohemia, NY, USA)
- In-Ovation R GAC brackets 0.022" slot Roth prescription (GAC Orthodontics, Bohemia, NY, USA)
- Damon 3MX brackets 0.022" slot Roth prescription (ORMCO, Glendora, CA, USA)
- Mirror

- Probe
- Mitchell's trimmer
- Molar bands (GAC Orthodontics, Bohemia, NY, USA)
- Intact glass ionomer cement (OrthoCare, Bradford, West Yorkshire, UK)
- Second molar tubes (American Orthodontics, Wisconsin, USA)
- Second molar tube holder (TP Orthodontics Inc., La Porte, IN, USA)
- Direct Bond eyelet brackets (TOC, Bristol, UK)
- 0.014" copper nickel titanium archwire (ORMCO, Glendora, CA, USA)
- 0.018" copper nickel titanium archwire (ORMCO, Glendora, CA, USA)
- 0.016" x 0.022" stainless steel archwire (GAC Orthodontics, Bohemia, NY, USA)
- 0.019" x 0.025" stainless steel archwire (GAC Orthodontics, Bohemia, NY, USA)
- Archwire stop (2mm) (ORMCO, Glendora, CA, USA)
- Weingart's utility pliers
- Distal end cutter
- Artery forceps
- Brit-ties (OrthoCare, Bradford, West Yorkshire, UK)
- Stainless steel ligatures
- Long ligatures
- NiTi Coil Springs 150g (GAC Orthodontics, Bohemia, NY, USA)
- Open coil spring pushcoil (SS) (Orthocare, Bradford, West Yorkshire, UK)
- Damon opening and closing tool
- System R opening and closing tool
- Cool tool
- Crimpable hook holder
- Crimpable hooks (TP Orthodontics Inc., La Porte, IN, USA)
- Tru-Force elastics (TP Orthodontics Inc., La Porte, IN, USA)
- Debonding Pliers
- Composite removal bur
- Contra angle slow handpiece (W&H, St. Albans, Hertfordshire, UK)
- Wax for bite and blocking out
- Perform-ID disinfectant for impressions (Schulke & Mayr UK Ltd, Sheffield, UK)
- 0.05% Fluoride mouthwash (Orthocare, Bradford, West Yorkshire, UK)

- Stopwatch

3.2 Materials used in the non-clinical environment

- Novadur extra hard dental stone (South West Industrial Plasters, Wiltshire, UK)
- Plaster bowl
- Spatula
- Dual Wheel model trimmer (Gamberini SRL, Casalecchio di Reno, Italy)
- Digital Vernier callipers (Fred V. Fowler Co., Inc., Newton, MA, USA)
- Study model storage boxes

3.3 Power Calculation

This study is a continuation of an investigation which commenced in 2006 (Clover 2008). Therefore when this study was designed, there were no existing studies reporting the standard deviation (SD) for the rate of initial alignment comparing self-ligating and conventional brackets. Consequently a power calculation was undertaken based on previous results of a study investigating space closure using NiTi coil springs with conventional brackets (Dixon *et al.* 2002). Here the mean rate of space closure with NiTi coil springs with conventional brackets was 0.81 mm per month and with a standard deviation of 0.51 mm.

Using this data it was estimated that 90 subjects, 18 with conventional brackets and 36 with both the passive and active self-ligating brackets were necessary to give an 80% power and a level of significance of 0.05 to detect a 0.3 mm difference in space closure between the different bracket types and therefore on any outcome. To allow for a 10% dropout rate, it was therefore planned to recruit 100 patients into the trial.

3.4 Method of Investigation

Local Research Ethics Committee (06/02202/6) and Research and Development (N23270/1) approvals were obtained from the Taunton and Somerset's Clinical Ethics Committee and the Research and Development Executive Group respectively prior to commencement of this clinical trial.

Patients who were ready to commence orthodontic treatment at the Orthodontic Department, Musgrove Park Hospital, Taunton, were assessed on their eligibility for inclusion in the trial. The flow of patients is shown in the CONSORT diagram (Figure 8) and the inclusion criteria were as follows:

- No medical history to contraindicate the placement of orthodontic bonds and bands
- Upper and lower premolar extractions required in all four quadrants
- Upper and lower fixed appliances required
- Under the age of 18 years at the start of treatment

The principal exclusion criteria were as follows:

- Subjects with learning difficulties
- Subjects who did not understand English
- Subjects with incomplete labial segments

All eligible subjects were given an information sheet describing the purpose of the trial (Appendix 1) at the treatment planning appointment as were accompanying parents or guardians (Appendix 2). This was done at least six weeks prior to the bond up appointment in order to allow the patient and or their parents/ guardians the opportunity to ask the researcher any relevant questions regarding the trial.

Interested eligible subjects and their accompanying parent or guardians, were then asked to give their written consent at the start of their bond-up appointment (Appendix 3) in order to participate.

Just prior to the bond-up the local Research and Development department was contacted to determine the subject's study number and allocated bracket type. Each subject was randomly allocated to one of three groups: the control group (n=20) with conventional brackets, or one of the two experimental groups: Damon 3MX (n=42) or In-Ovation R (n=38). The randomisation process also took into consideration the following patient variables:

Patient Age:

Two groups: 11 to 14 years old

15 to 18 years old

Frankfort Mandibular Planes Angle:

Three groups: Low < 22°

Average 22° to 32°

High > 32°

Cephalometric analysis of the pre-treatment lateral skull radiograph was used to determine the Frankfort Mandibular Planes Angle.

Block randomisation was used to ensure subjects were randomly allocated into the three arms of the trial in order to facilitate stratified randomisation. This process was carried out solely by the research and development department in Taunton, to allow blinding of the researchers and to prevent the possibility of prediction of the next randomisation within each block.

All of the subjects were treated at Musgrove Park Hospital by named operators. These included three consultants (CNM, NEA, HSG) and five specialist registrars (MJC, NAW, RW, MPD, GS).

Initial pre-treatment impressions were obtained prior to bond-up using Orthoprint alginate impression material (Zhermack, Rovigo, Italy). The dental laboratory was informed and the impressions were cast up within one hour, using extra hard dental stone (Novadur, South West Industrial Plasters, Wiltshire, UK). They were labelled with the date of the impression, the subject's study number and then stored in study model boxes.

3.5 The bond-up appointment

Following the randomisation process into one of the three bracket groups, each subject had a full mouth bond up carried out using their assigned bracket type.

The bond-up was carried out following a standardised protocol:

1. Retraction of the soft tissues was achieved with the use of lip/ cheek retractors and moisture control was maintained using intra-oral suction.
2. All of the teeth were etched for 30 seconds each using 37% *o*-phosphoric acid, followed by rinsing with copious amounts of sterile water. Finally the enamel was dried until it was frosty white in appearance.
3. Transbond™ XT light cure adhesive primer (3M Unitek, Dental Products Division, Monrovia, CA, USA) was applied to the etched surfaces of the teeth. This was then either light cured or left uncured at the discretion of the operator.

4. Transbond™ XT light cure adhesive paste (3M Unitek, Dental Products Division, Monrovia, CA, USA) was applied to the appropriate bracket base by the dental assistant and each bracket was placed on the tooth by the operator. The bracket was pushed onto the tooth surface and any excess adhesive was removed using either a Mitchell's trimmer or probe. The order in which the brackets were placed was according to operator preference. Each tooth was light cured for 20 seconds (10 seconds per interproximal space) using either a Litex 695C light curing unit (DentAmerica, City of Industry, CA, USA) or a Mini LED Ortho (Satelec, Merignac, France). Where self-ligating brackets were used, there was no particular protocol regarding whether they were open or closed during bond up. However, they were all closed once the initial bond-up appointment was complete.
5. Following bond placement and curing, elastomeric separators (OrthoCare, Bradford, West Yorkshire, UK) were placed mesially and distally to the first molars in all quadrants, as required. All subjects were given routine aftercare information and advised to use a 0.05% Fluoride mouthwash daily. An initial bottle of Fluoride mouthwash was provided to every patient.
6. Subjects returned to the department for the band and archwire placement one week after the initial bond placement and separation. First molar bands (GAC Orthodontics, Bohemia, NY, USA) were cemented using Intact glass ionomer cement (OrthoCare, Bradford, West Yorkshire, UK). The order in which these were placed was again left to the discretion of the operator. If specific treatment plans required the placement of a transpalatal arch, lingual arch or quadhelix then bands were placed *in situ*, impressions obtained and elastomeric separators replaced. These appliances were then cemented one week later using Intact glass ionomer cement and initial archwires placed at this appointment.

If it was not possible to place a bracket in the ideal position on the labial surface of a tooth (e.g. in cases of severe crowding), then clinical discretion was used to reach a decision, options included;

1. To bond the tooth and accept that the bracket would have to be repositioned at a later date.
2. To bond an eyelet on the tooth surface and ligate it to the archwire with a Stainless Steel ligature (with or without pushcoil).
3. To place pushcoil initially and make space to allow the placement of the bracket in the ideal position on the labial surface of the tooth at a later date.

The specific mechanics chosen had no impact on the inclusion or exclusion of the subject to the trial.

The first archwire for all subjects (following bonding and banding) was a 0.014" Copper Nickel Titanium (ORMCO, Glendora, CA, USA). This was ligated to conventional brackets using elastomeric modules (Brit-Ties) (Orthocare, Bradford, West Yorkshire, UK). When self-ligating brackets were used all brackets were fully closed. To prevent the archwire from swivelling, 2mm archwire stops (ORMCO, Glendora, CA, USA) were placed on both the upper and lower archwires. These were placed in sites where they would not interfere/ hinder alignment. The most common position for the lower archwire was a single stop placed in between the lower central incisors, and in the upper archwire two stops were usually placed either side of an incisor bracket. Lacebacks were not permitted during the initial alignment phase as "active" lacebacks, which could not be reproducibly placed, would retract the canines and affect the rate of labial segment alignment.

3.6 Routine Appointments

Subjects in the conventional group were recalled every 6 weeks, as is custom and practice. Whereas the remaining subjects in both of the self-ligation groups were recalled every 12 weeks. This time frame was selected to reflect the recommended recall period suggested by the manufacturers of the Damon 3MX brackets.

Archwires were changed when clinically indicated, and the following archwire sequence was used for all of the subjects within the study:

- 0.014" Copper Nickel Titanium archwire (ORMCO, Glendora, CA, USA)
- 0.018" Copper Nickel Titanium archwire (ORMCO, Glendora, CA, USA)
- 0.016" x 0.022" Stainless Steel archwire (GAC Orthodontics, Bohemia, NY, USA)
- 0.019" x 0.025" Stainless Steel archwire (GAC Orthodontics, Bohemia, NY, USA)

Active space closure was carried out on a 0.019" x 0.025" Stainless Steel archwire in both the upper and lower arches. Crimpable archwire hooks were placed between the lateral incisor and canine bracket in all four quadrants when required and space closure was carried out using a 150g NiTi coil springs and sliding mechanics. When space closure in a quadrant was complete, a passive long ligature was placed from the first molar to the crimpable hook to prevent the space from reopening.

The use of intra-oral elastics was permitted where clinically justified. This was usually once the subjects were in a Stainless Steel archwire.

The second molars were not routinely included in the initial bond-up. However, if it was clinically justified as part of the treatment plan, then upper and lower second molars were bonded with molar tubes following the same bonding protocol as used in the initial bond-up appointment.

Upper and lower alginate impressions were taken of all subjects every 12 weeks until the end of treatment. Beading wax was used to block out the brackets and archwire to facilitate the easy removal of the impression. This also enabled the bracket type to remain anonymous when impressions were subsequently cast in stone. All impressions were cast within one hour in the dental laboratory.

3.7 Emergency Appointments

If a subject presented for an emergency visit, the appliance was repaired using the same bracket type and archwire. This could be undertaken by any named operator in the study (CNM, NEA, HSG, MJC, NAW, RW, MPD and GS). The same bonding protocol was used as in the initial bond-up appointment, and if possible, the same archwire replaced. If complete

engagement of the archwire could not be achieved, then the previous wire size within the agreed archwire sequence that could be fully engaged was fitted.

3.8 Measurement of Labial segment alignment

A previous study looking at the accuracy of measuring labial segment alignment recommended the use of digital Vernier callipers (Clover 2008). Therefore, Little's Index of Irregularity was measured for each subject using their study models, at each 12 week period of the study using a digital Vernier calliper (Fred V. Fowler Co., Inc., Newton, MA, USA) by a single researcher (GS). Prior to this part of the study a reproducibility study was undertaken. The Little's Index on 10 randomly selected models were measured on two occasions one week apart by the same operator (GS) using the Vernier callipers.

Following the repeatability study the contact point displacements were measured to within 0.01mm from the mesial of the right canine to the mesial of the left canine in the upper dental arch and from the mesial of the left canine to the mesial of the right canine in the lower dental arch. In order to ensure consistency each model set was measured with the bases placed on a flat surface and back to back. All measurements were made from above in a clockwise direction starting from the upper right canine and ending at the lower right canine. The sum of contact point displacements was calculated for each dental arch, for each subject, at every 12 week period until the end of treatment. The data were transferred into an Access Database 2007 (Microsoft Corp., Seattle, USA).

3.9 Measurement of Space Closure

Extraction space in all four buccal quadrants was measured using the subject's study models at the start and at each 12 week period until the end of treatment, using the same digital Vernier calliper again by a single researcher (GS). It was measured from the buccal groove of the first molar to the distal contact point of the corresponding canine in each quadrant. To ensure repeatability, each model was placed on a flat surface and the space measured from above and to within 0.01mm under similar conditions. For every subject the measurements were carried out in a clockwise direction starting with the upper right quadrant. All of the measurements were then entered into an Access Database 2007 (Microsoft Corp., Seattle,

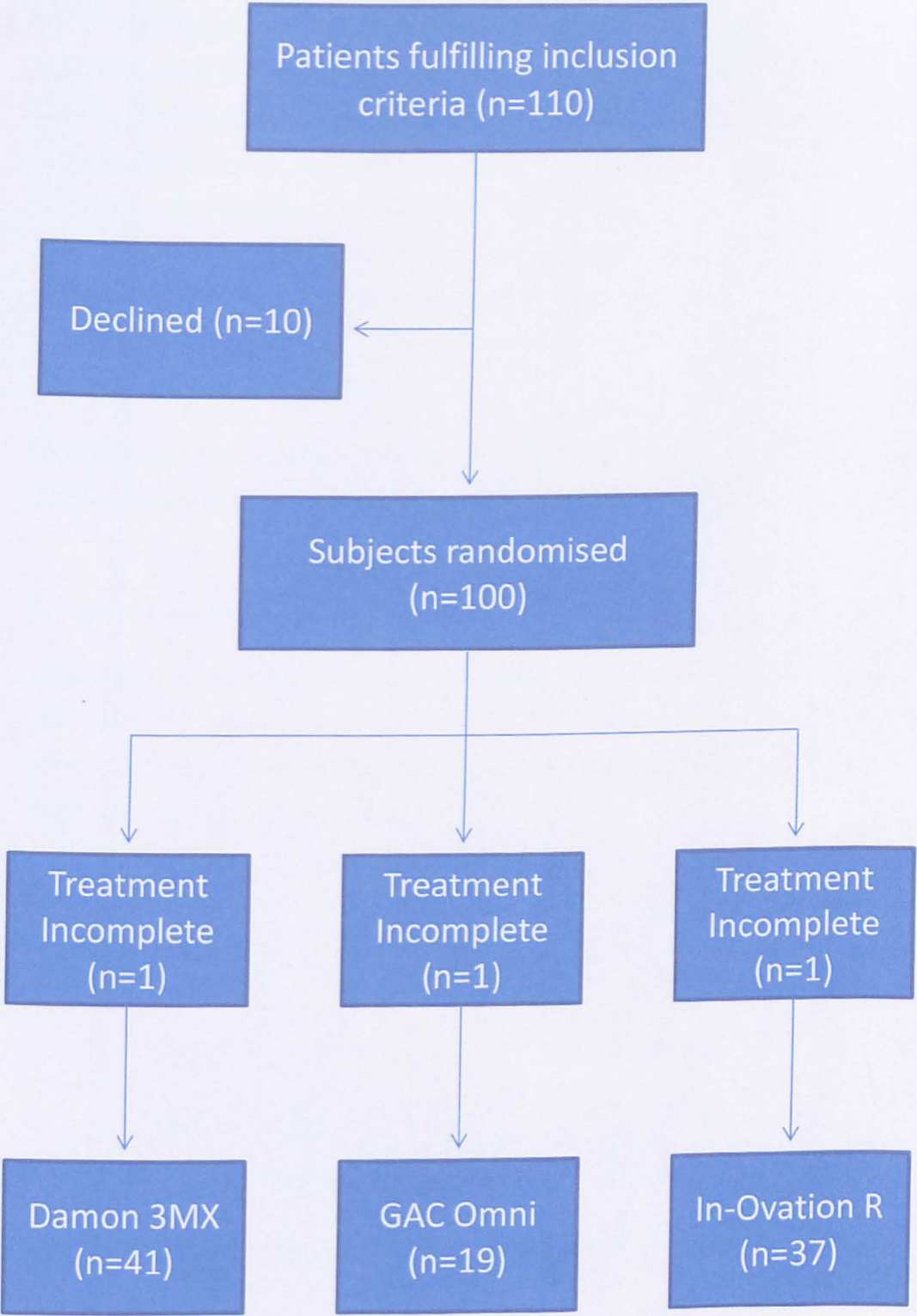
USA). As with the Little's Index a repeatability study was performed by measuring the space on 10 randomly selected models by the same operator (GS) on two occasions one week apart.

3.10 Measurement of appointment treatment times

Along with the measurements of labial segment alignment and buccal space closure, a number of other factors were investigated and measured during this study. Each appointment for every subject was timed using a stopwatch from the point of 'probe to tooth' to 'ligation of the last bracket'. This was measured to the nearest second using a stopwatch and recorded in the patients notes. Each appointment was also logged in a study book for every subject including all emergency appointments.

4 Consort Diagram

Figure 8 Consort diagram charting the flow of subjects through the trial



5 Results

The data were analysed using Stata Version 11 (Stata Corp., College Station, Texas, USA) with a predetermined level of significance in most cases of $\alpha=0.05$. Age distribution was tested using the Kolmogorov-Smirnov test for equality and bracket distribution using the χ^2 test. Initial alignment and subsequent space closure was investigated using linear mixed models and False Discovery Rate (Simes FDR) multiple comparison tests. The advantage of using linear mixed models over conventional repeated measures ANOVA is that the mixed model allows missing data within a patient, whereas in conventional ANOVA any missing data means that patient will be excluded from the analysis. Repeatability of measurement of Little's Index of incisor alignment and subsequent space closure were tested using Lin's concordance correlation coefficient.

Treatment times and breakage data demonstrated residuals that were not normally distributed and so a non-parametric Kruskal Wallis one way analysis of variance was used in each case.

5.1 Age and sex distribution for the trial

The summary statistics for age and sex distribution are illustrated in Table 2. Approximately two thirds of the patients enrolled into the study were female and one third male. Using the Kolmogorov-Smirnov test for equality there was no significant difference in the age distribution within each of the two groups ($p=0.71$).

Sex	N	Mean	SD	Min	Max
Female	63	13.96	1.37	11.00	16.92
Male	37	14.21	1.20	11.75	17.08
Total	100	14.05	1.31	11.00	17.08

Table 2 Summary statistics for age and sex distribution of the study subjects

5.2 Bracket distribution

There were three brackets under test within this trial, namely the non self-ligating Siamese Omni brackets, the Damon 3MX and the In-Ovation R brackets. Using the Chi squared test there was no statistically significant difference in the bracket distribution within the two groups, male or female ($p=0.68$). The distribution is shown in Table 3 and illustrated in the histogram, Figure 9.

Bracket	Female	Male
Damon 3MX	25	17
In-Ovation R	26	12
Omni	12	8

Probability $< \chi^2 = 0.68$

Table 3 Bracket distribution within male and female subjects

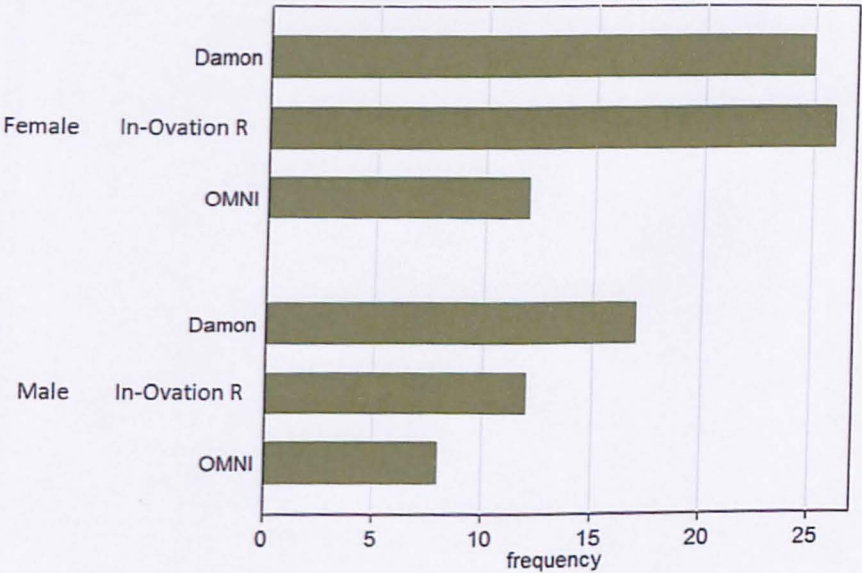


Figure 9 Histogram illustrating the bracket distribution within sex, Damon 3MX, In-Ovation R and conventional Omni bracket

5.3 Frankfort Mandibular Planes Angle (FMPA)

As rate of tooth movement is influenced by the FMPA, it was decided to test the relationship between FMPA (low, average or high) and sex (Table 4 and Figure 10) using the Chi squared test and also between FMPA and bracket type using the same test (Table 5 and Figure 11). In both cases there was no statistically significant difference in the distribution of FMPA with sex ($p=0.44$) or bracket type ($p=0.99$).

FMPA	Female	Male
Low	5	5
Average	40	25
High	18	7

Probability $< \chi^2 = 0.44$

Table 4 FMPA within male and female subjects

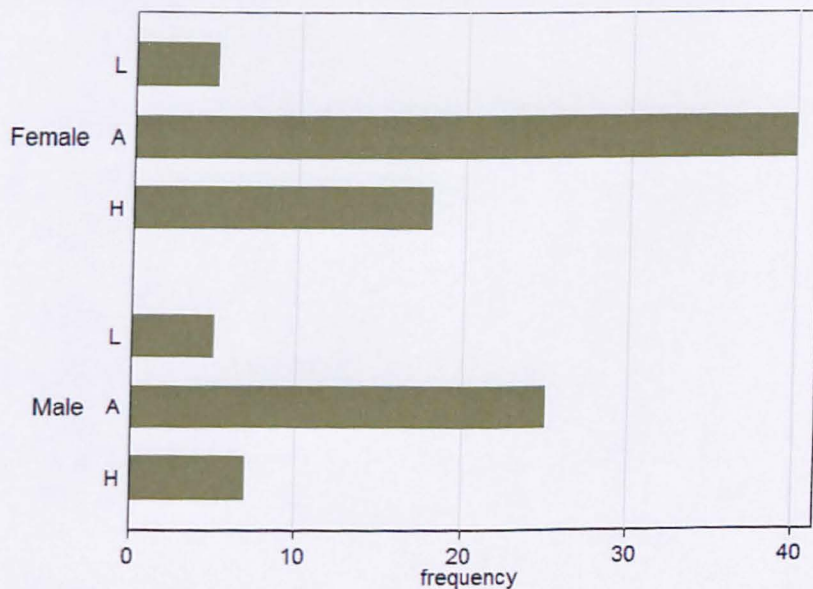


Figure 10 Histogram illustrating the FMPA distribution within sex. Code L = Low, Code A = Average and Code H = High

	Brackets		
FMPA	Damon 3MX	In-Ovation R	Omni
Low	4	4	2
Average	27	25	13
High	11	9	5

Probability < $\chi^2 = 0.99$

Table 5 FMPA within bracket type

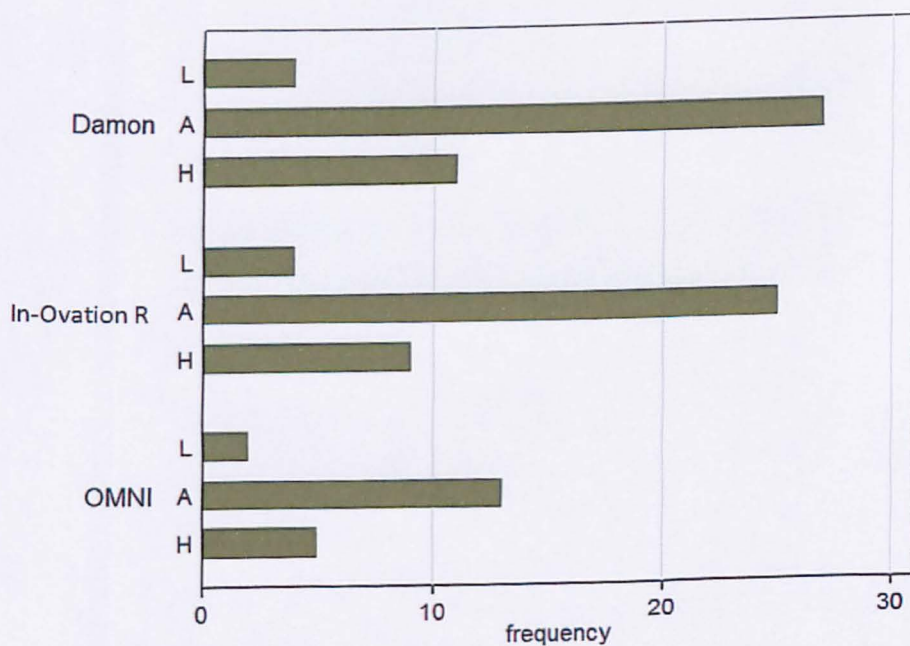


Figure 11 Histogram illustrating the FMPA distribution within bracket, Damon 3MX, In-Ovation R and conventional Omni bracket

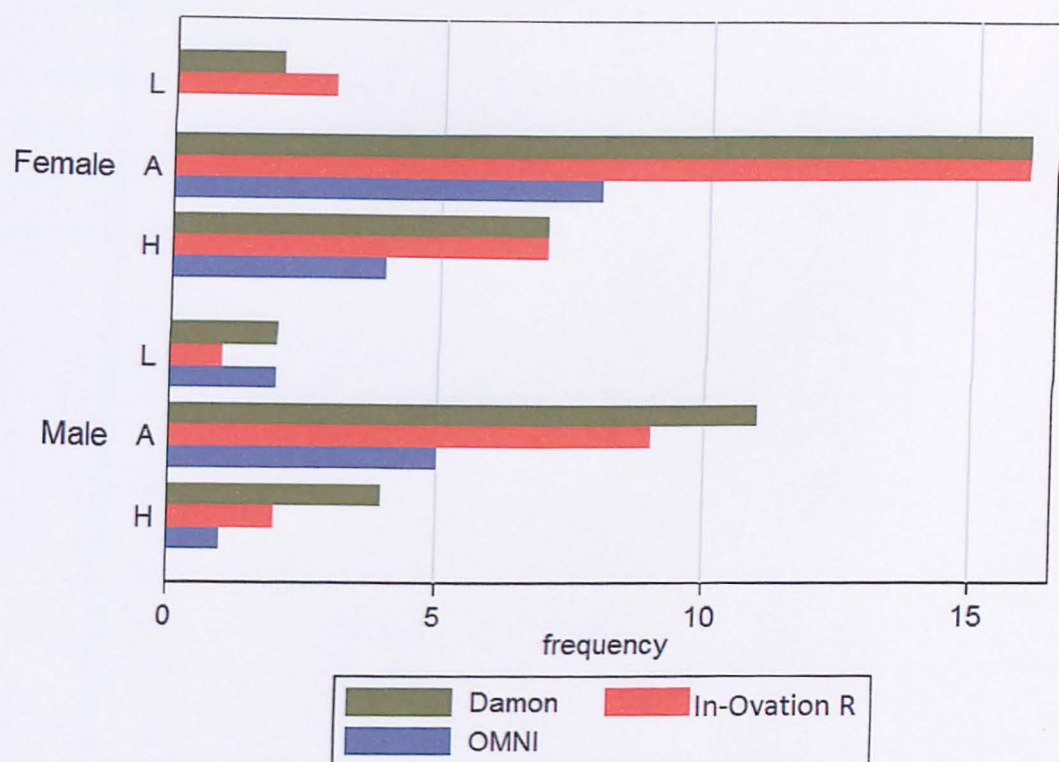


Figure 12 Histogram illustrating the FMPA distribution within sex and bracket, Damon 3MX, In-Ovation R and conventional Omni bracket

5.4 Repeatability of measurement using the Vernier callipers

5.4.1 Little's Index

Repeatability of measurement of Little's Index of Irregularity was tested using Lin's concordance correlation coefficient (Lin 1989, 2000), which showed almost perfect agreement between the measurements at T1 and T2 by the single operator (GS). The concordance plot is shown in Figure 13.

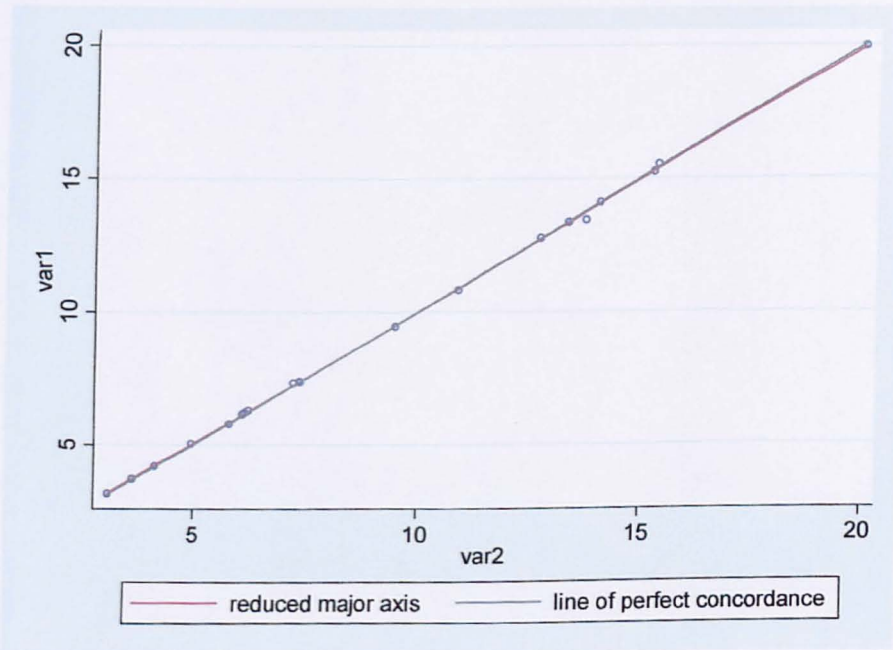


Figure 13 Lin's concordance correlation coefficient plot for Little's Index measured using digital Vernier callipers at T1 and T2

rho_c	SE(rho_c)	Obs	[95% CI]		P	CI type
1.000	0.000	20	1.000	1.000	0.000	asymptotic
			1.000	1.000	0.000	z-transform

Difference		95% Limits Of Agreement	
Average	Std Dev.	(Bland & Altman, 1986)	
-0.004	0.095	-0.190	0.182

5.4.2 Space Closure

Repeatability of measurement of space closure was also tested using Lin’s concordance correlation coefficient (Lin 1989, 2000) and again showed almost perfect agreement between the measurements at T1 and T2 by the single operator (GS). The concordance plot is shown in Figure 14.

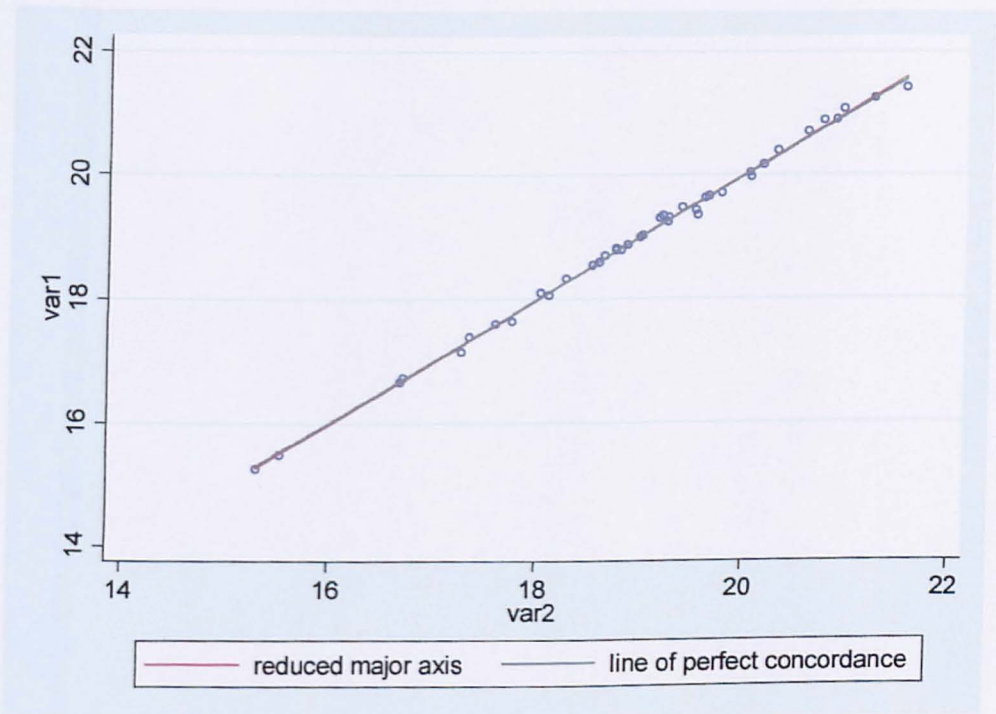


Figure 14 Lin’s concordance correlation coefficient plot for Space Closure measured using digital Vernier Callipers at T1 and T2

rho_c	SE(rho_c)	Obs	[95% CI]		P	CI type
0.999	0.000	40	0.998	0.999	0.000	asymptotic
			0.997	0.999	0.000	z-transform

Difference		95% Limits Of Agreement	
Average	Std Dev.	(Bland & Altman, 1986)	
0.002	0.076	-0.146	0.151

5.5 Labial segment alignment

An important aspect of any trial comparing initial alignment is the degree of malalignment of the teeth prior to treatment. It is particularly important this malalignment is similar in each treatment group. Using a one way analysis of variance there was no statistically significant difference in the pre-treatment Little's Index between the groups ($p=0.234$). This is illustrated by the means and 95% confidence intervals of the mean in Figure 15.

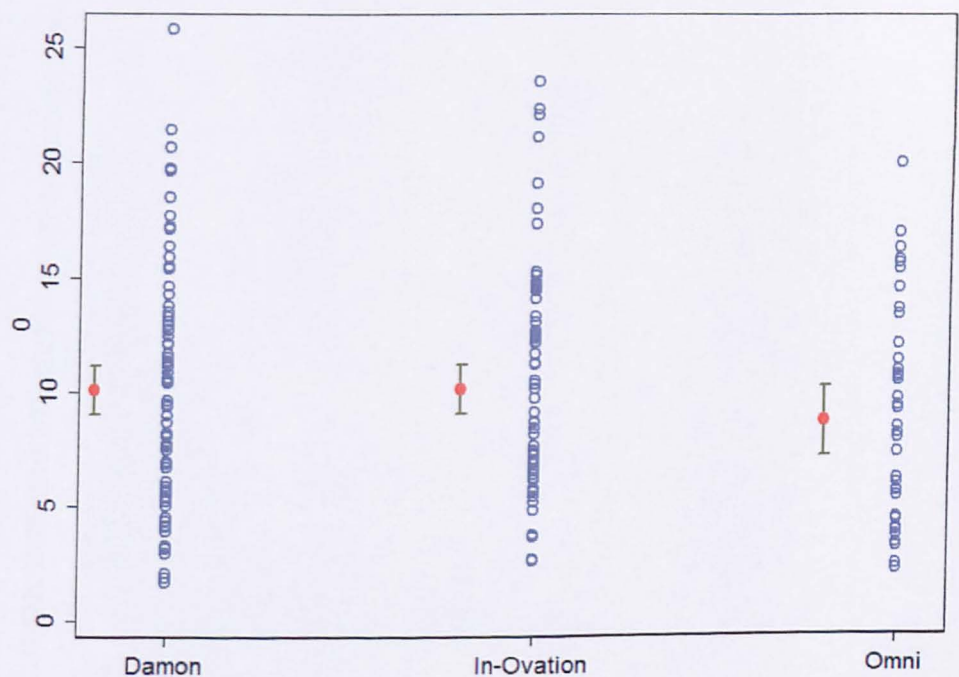


Figure 15 Means, 95% confidence intervals of the mean and raw data for the combined upper and lower labial segment Little's Index scores for the patients in each of the three bracket treatment groups

5.5.1 The effect of bracket type on alignment

The effect of bracket type on alignment was performed by measuring Little's Index from permanent canine to canine in both the maxilla and the mandible using study models taken at intervals of 12 weeks. The data were analysed using linear mixed models (West *et al.* 2007). The following are the distributional plots for the combined brackets in the maxilla and mandible and then separate plots each of the brackets under test (maxillary and mandibular data combined). In each case these are the plots for all the patients and both upper and lower arches.

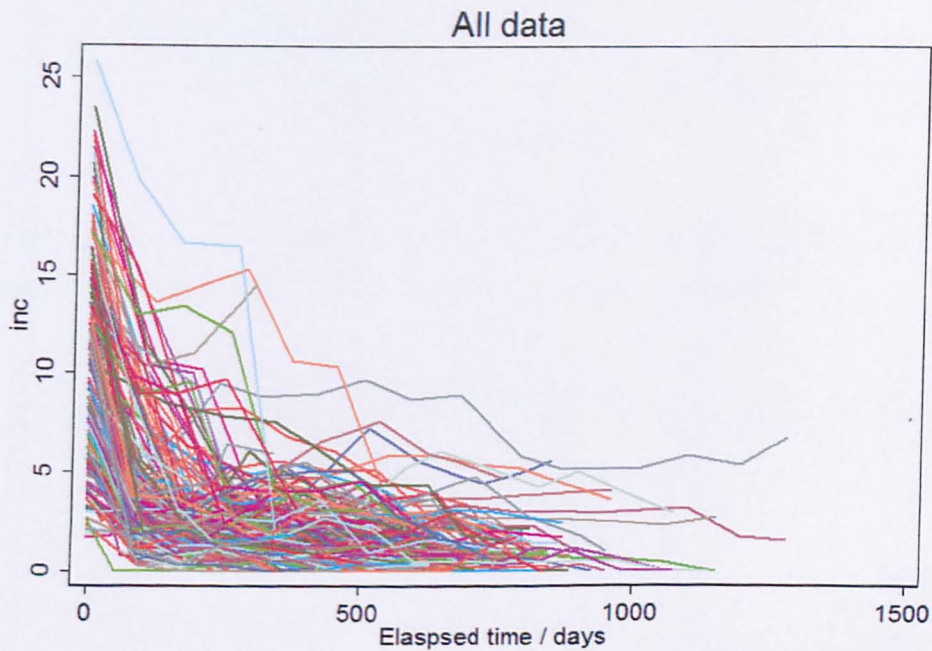


Figure 16 Distributional plot of the initial alignment over time (days) for all the patients with all three bracket types in both the mandible and maxilla (200 observations)

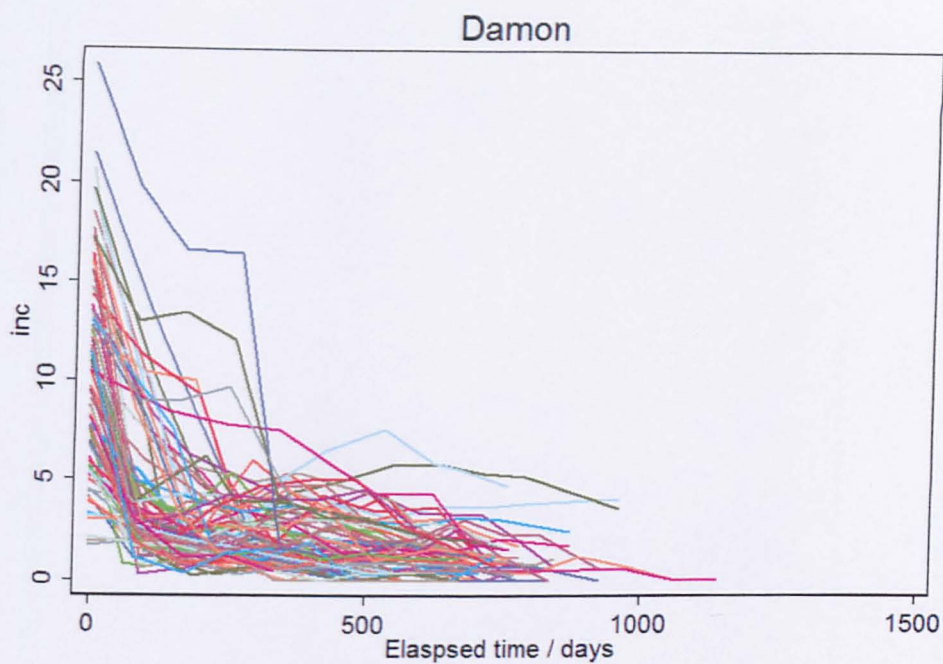


Figure 17 Distributional plot of the initial alignment over time (days) for all the patients with the Damon 3MX bracket both mandible and maxilla

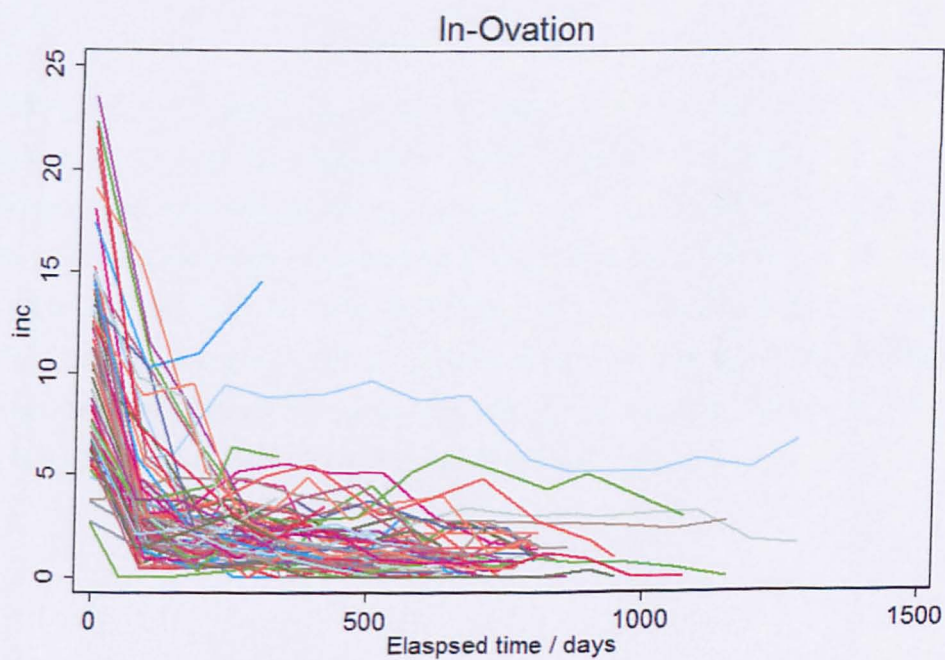


Figure 18 Distributional plot of the initial alignment over time (days) for all the patients with the In-Ovation R bracket both mandible and maxilla

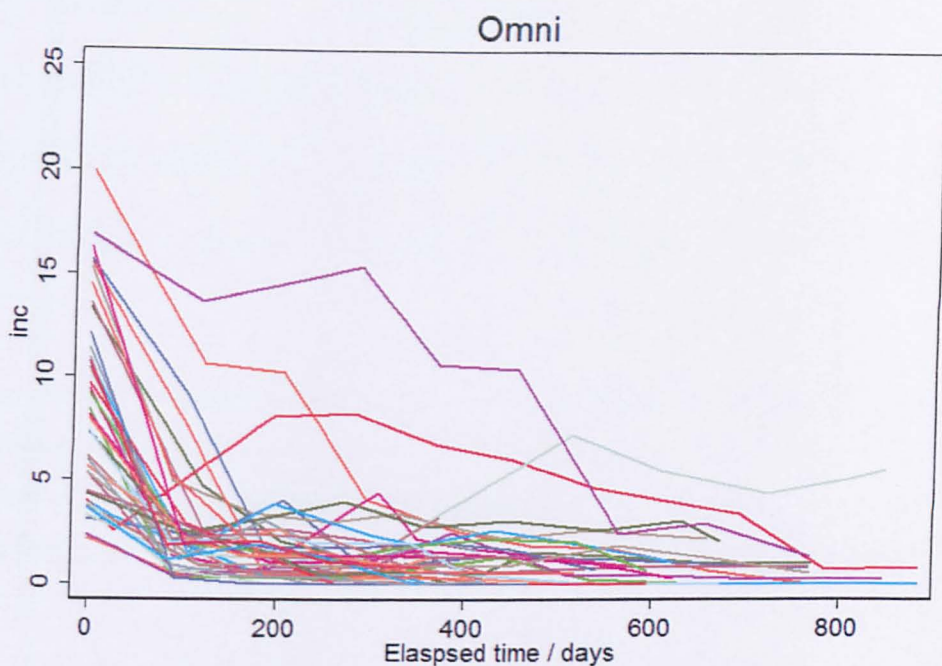


Figure 19 Distributional plot of the initial alignment over time (days) for all the patients with the Omni bracket both mandible and maxilla

The linear mixed model analysis showed there to be a significant effect of both bracket type ($p=0.01$) and jaw (*i.e.* maxilla or mandible) ($p=0.001$) on the rate of initial tooth alignment in the labial segments. Interestingly, bracket type had an effect on initial alignment in the mandible ($p=0.026$) but not the maxilla ($p=0.277$) and this difference between the jaws was significant for each bracket type (Damon 3MX $p=0.001$, In-Ovation R $p=0.001$, Omni $p=0.001$). A pairwise comparison of the initial alignment for each bracket type showed there to be a significant difference between the conventional Omni bracket and the two self-ligating brackets, Damon 3MX and In-Ovation R (Table 6).

Comparison	Coefficient	Std Err	Z	p>[z]	95 % CI
Damon 3MX vs. In-Ovation R	0.158	0.277	0.571	0.568	-0.384 to 0.701
Damon 3MX vs. Omni	1.023	0.344	2.97	0.003	0.348 to 1.699
In-Ovation R vs. Omni	0.866	0.350	2.47	0.013	0.179 to 1.552

Table 6 Pairwise comparison showing there is no statistically significant difference in the rate of initial alignment between the two self-ligating brackets. There was a statistically significant difference in the rate of initial alignment between these two brackets and the conventional Omni bracket

In order to test the effect of bracket type further a multiple comparison test was used. Instead of using a more traditional approach such as Family Wise Error Rate (FWER) *e.g.* Bonferroni, which can be rather conservative, it was decided to use the more recent False Discovery Rate (FDR). This approach controls the number of false positives in those tests that result in a significant result (discovery) and means they have a greater ability (power) to detect truly significant results. The approach uses q-values which are the adjusted p-values. In these tests we have used Simes FDR (1986) method for multiple comparisons and it shows there to be a significant difference between the Omni bracket and the two self-ligating brackets (Figure 20) with the rate of initial alignment being significantly faster with the Omni bracket and no statistically significant difference between the two self-ligating brackets.

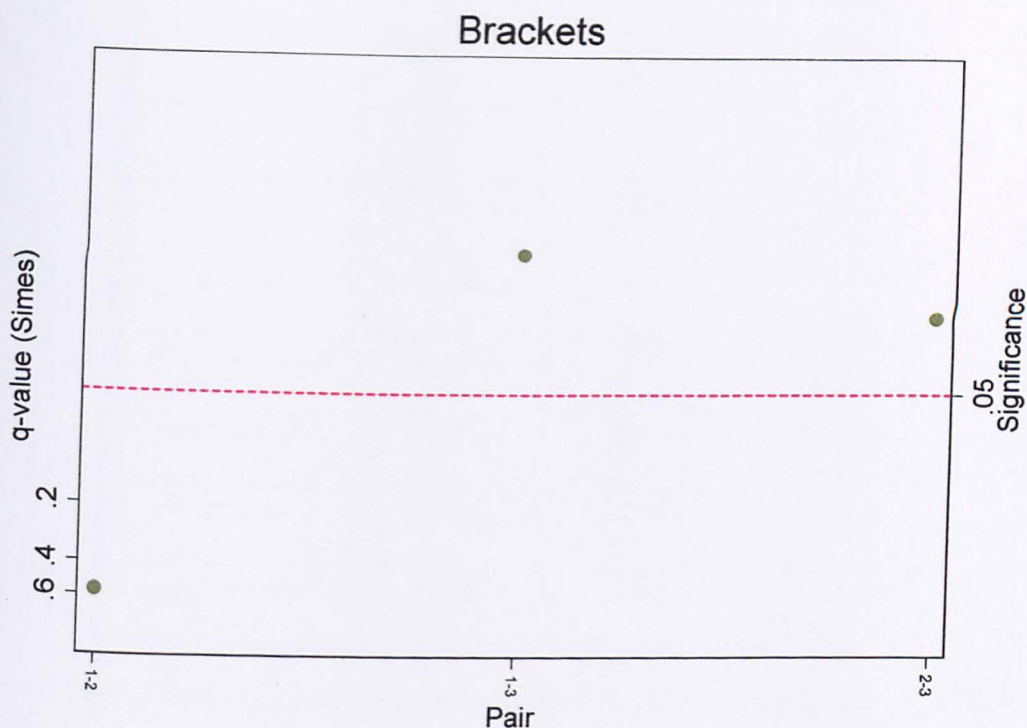


Figure 20 Plot of the q-values against bracket pairing. In this plot anything above the 0.05 line is a significant difference (Pairings: Code 1 = Damon 3MX, Code 2 = In-Ovation R and Code 3 = conventional Omni bracket)

5.6 The effect of bracket type on space closure

It was decided to determine the effect of factors and their interactions on the observed space closure along with a direct comparison of bracket type ignoring all other factors. The results indicated there was no significant effect of FMPS so it was omitted from the model. Table 7 shows the summary of the interactions for space closure within each bracket. With the Damon 3MX bracket there was a significant interaction with jaw in the female group but no significant effect overall with sex. With the In-Ovation R there was no significant effect of jaw but there was with sex. With the Omni bracket there was a significant effect of both sex and jaw.

Effect	Damon 3MX	In-Ovation R	OMNI
jaw	0.015	0.873	0.001
sex	0.155	0.001	0.003
jaw#sex	0.670	0.001	0.096
sex at mandible	0.139	0.001	0.015
sex at maxilla	0.189	0.001	0.001
jaw at female	0.023	0.001	0.272
jaw at male	0.198	0.001	0.001

Table 7 Summary table of the effects and interactions tested using linear mixed models within each bracket type

Table 8 shows the probabilities for the pairwise comparisons for the effect of bracket on space closure. The q-plot using the linear mixed model is illustrated in Figure 21. The exact probabilities in Table 8 and the q-plot demonstrate there is no statistically significant difference in the rate of buccal segment space closure for each of the three brackets under test.

Bracket pair	Probability
Damon 3MX ~ In-Ovation R	0.797
Damon 3MX ~ OMNI	0.751
In-Ovation R ~ OMNI	0.917

Overall probability $p = 0.941$

Table 8 Exact probabilities of the effect of bracket type on space closure

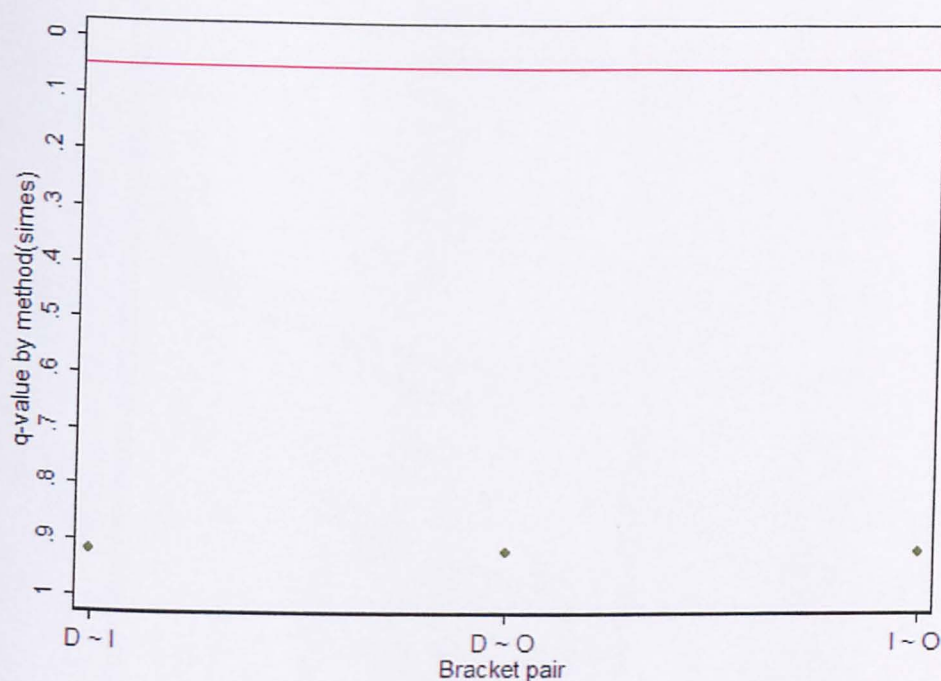


Figure 21 Plot of the q-values against bracket pairing. In this plot anything above the red 0.05 line is a significant difference (D = Damon 3MX, I = In-Ovation R and O = conventional Omni bracket)

Looking at each bracket separately, space closure was significantly faster in males than in females in the case of both the In-Ovation R ($p=0.001$) and the Omni brackets ($p=0.003$). Although not statistically significant in the case of the Damon 3MX brackets, the plot of space closure with time in each case still shows space closure to be quicker in males than in females. This is illustrated in Figures 22, 23 and 24.

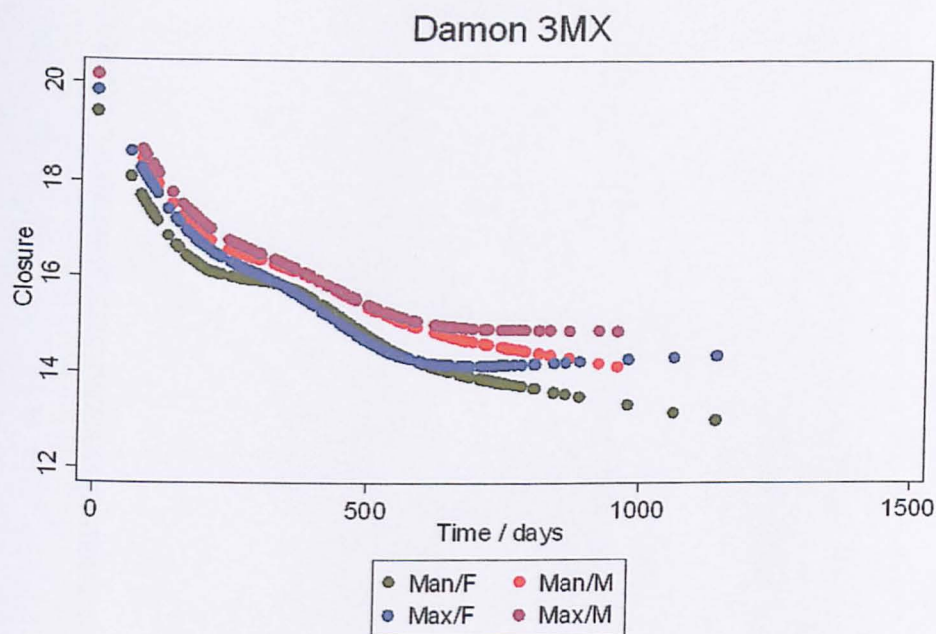


Figure 22 Plot of space closure (mm) against time (days) for the Damon 3MX brackets

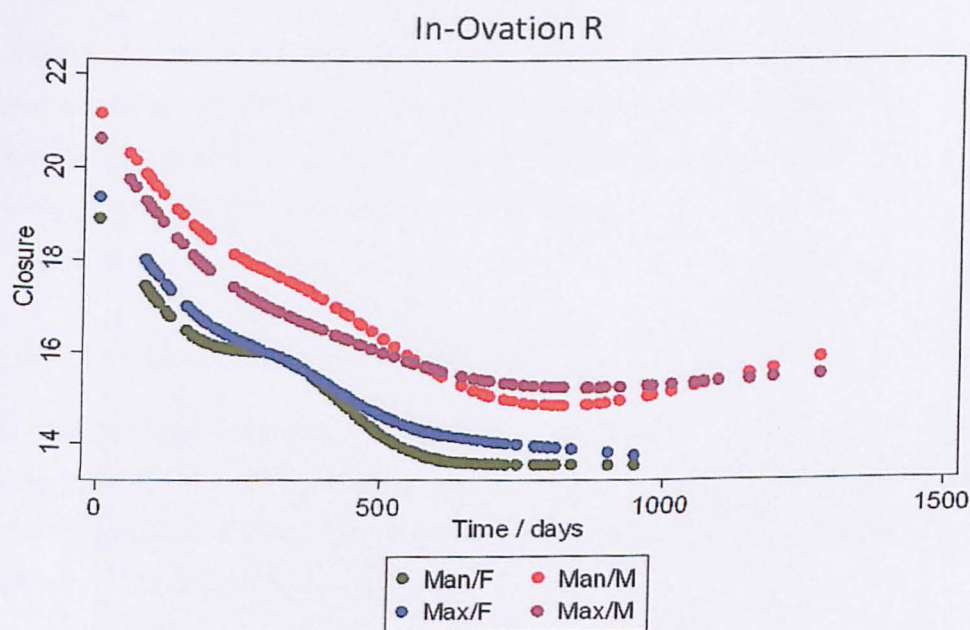


Figure 23 Plot of space closure (mm) against time (days) for the In-Ovation R bracket

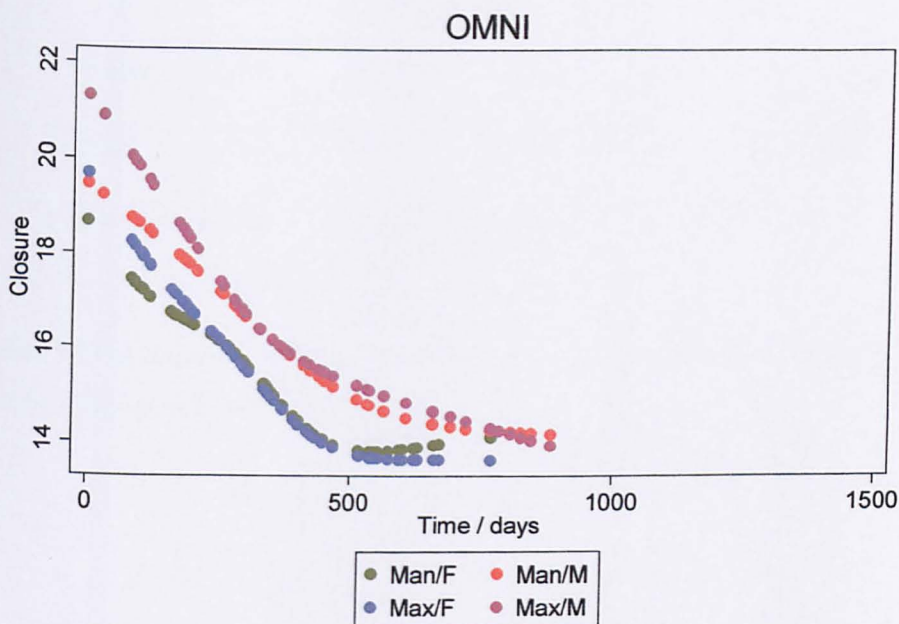


Figure 24 Plot of space closure (mm) against time (days) for the Omni bracket

In the case of the Damon 3MX bracket the effect of sex and jaw appears to be more pronounced at longer times and the maxilla appears to reach a steady state before the mandible. With both the In-Ovation R bracket and the Omni bracket the effect of sex appears more pronounced than with the Damon 3MX bracket.

5.6.1 The effect of sex on space closure

In order to further investigate the effect of sex on space closure the results of all three bracket types were pooled. The summary data are illustrated in Table 9. A student t-test showed there to be a significant difference between males and females ($p=0.001$), with space closure faster in males. This is illustrated in Figure 25.

Sex	Obs	Mean	Std. Err.	Std. Dev.	95% Conf. Interval
Female	252	19.44	0.135	2.144	19.17 to 19.71
Male	148	20.61	0.180	2.192	20.24 to 20.96
Combined	400	19.87	0.112	2.231	19.65 to 20.09

Table 9 Data summary table for space closure for sex (data from all three brackets pooled and for both maxilla and mandible)

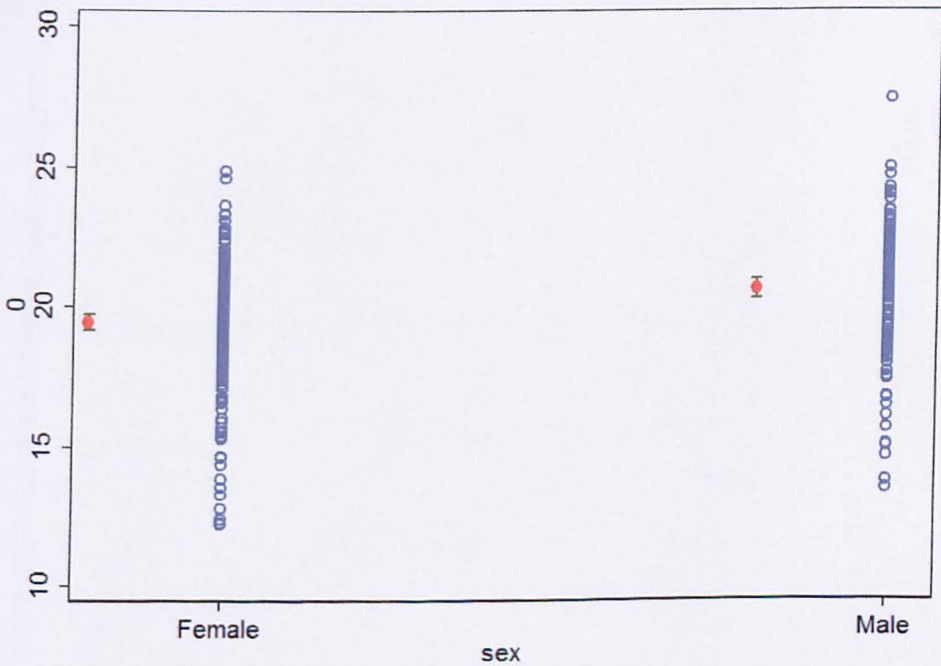


Figure 25 Means, 95% confidence intervals of the mean and raw data for the combined space closure (mm) for males and females

A further illustration and investigation of the effect of sex was sort using restricted cubic spline plots to fit the data (Harrell 2001). It was then differentiated numerically in order to determine the rate of closure. Within each plot the steeper the curve *the faster the rate of* space closure. The plots for each bracket type are shown in Figures 26, 27 and 28.

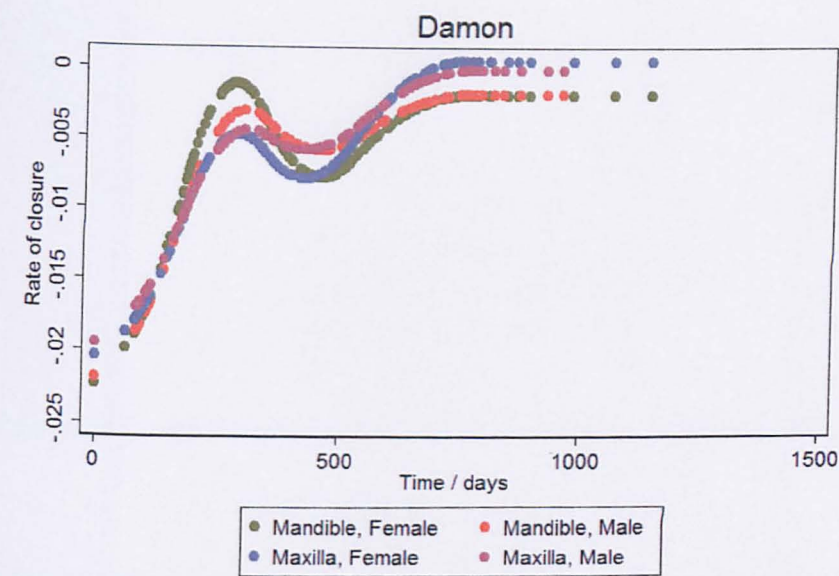


Figure 26 Restricted cubic spline plot of rate of space closure for the Damon 3MX bracket

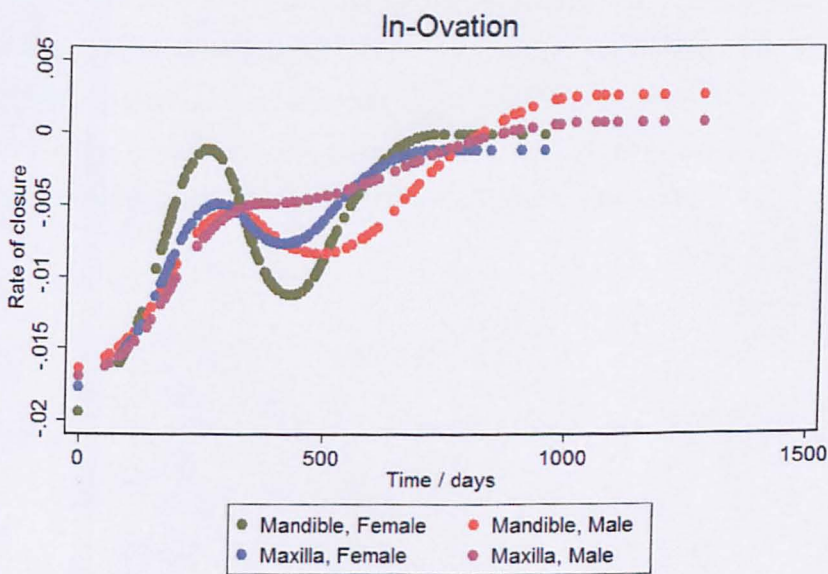


Figure 27 Restricted cubic spline plot of rate of space closure for the In-Ovation R bracket

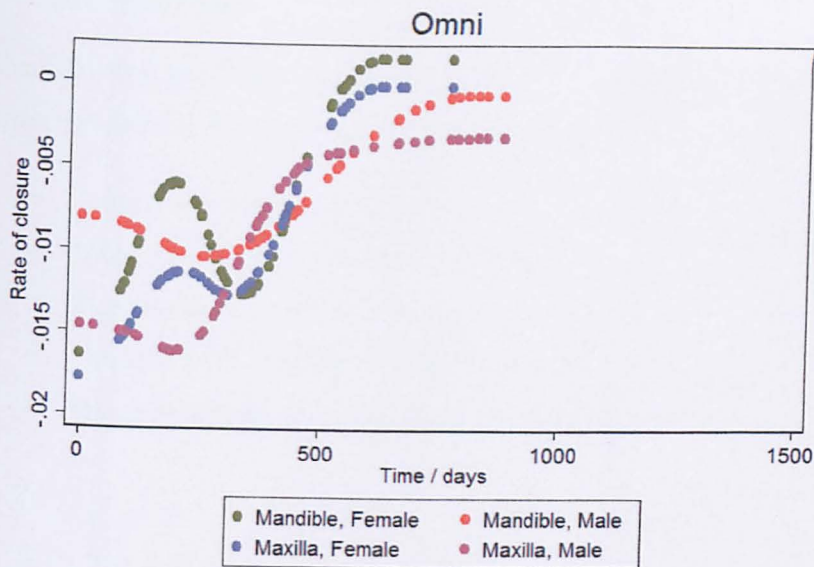


Figure 28 Restricted cubic spline plot of rate of space closure for the Omni bracket

Looking at the cubic spline plots it can be seen that the rate of space closure during treatment in the case of all three brackets is generally greater towards the earlier stages of treatment. However, the plots show that the rate of space closure is far from linear at all times. Indeed at some points there is a reversal of the rate of space closure which seems to be a consistent finding with all three brackets. This could be the time between initial alignment, when simultaneous space closure is taking place, and the placement of active space closing mechanics. What is also interesting from the cubic spline plots is that the effect of sex is more pronounced in the case of the In-Ovation R and the Omni brackets.

5.7 Treatment Times

The following treatment time parameters were studied and the data analysed in each case using the Kruskal Wallis non-parametric one way analysis of variance:

- Total chair side time in minutes
- Mean treatment time per visit in minutes
- The overall treatment time in days
- The total number of appointments to debond
- The total number of emergency appointments

5.7.1 Total chair side time in minutes

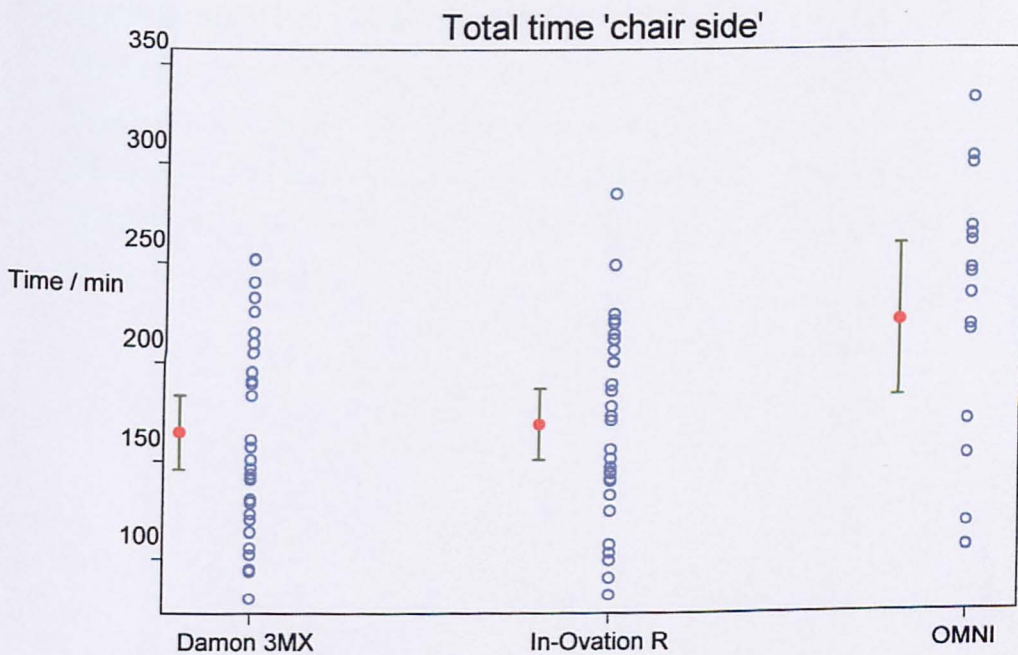


Figure 29 Means, 95% confidence intervals of the mean and raw data for total chair side time in minutes for each of the three brackets under test

Bracket	N	Mean	SD	Min	Max
Damon 3MX	30	164.39	50.88	79.77	251.68
In-Ovation R	31	168.82	49.40	81.48	284.90
OMNI	16	220.37	71.67	104.63	332.10

Table 10 Summary data of Total Chair Side time for patients who had completed treatment

The Kruskal Wallis non-parametric one way analysis of variance demonstrated a statistically significant difference between the groups ($p=0.013$). Further analysis using the Mann-Whitney test demonstrated no significant difference between the Damon 3MX and In-Ovation R brackets ($p=0.39$). There was a statistically significant difference between the Damon 3MX and the Omni brackets ($p=0.003$) and the In-Ovation R and the Omni brackets ($p=0.005$) with the total chair side treatment being greater in the case of the Omni bracket and by around 50 minutes.

5.7.2 Mean treatment time per visit in minutes

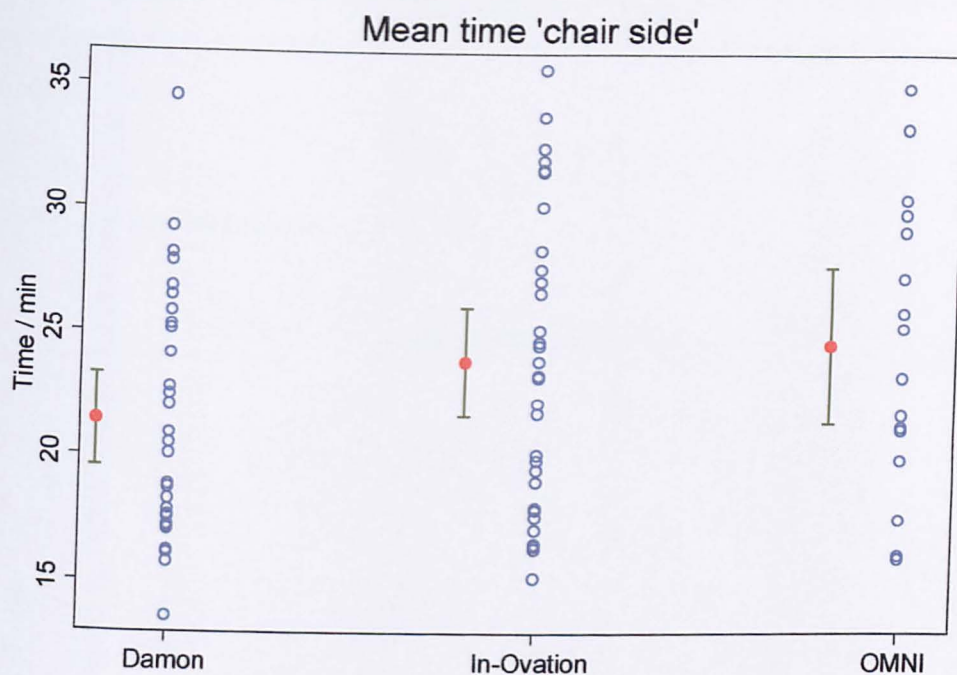


Figure 30 Means, 95% confidence intervals of the mean and raw data for chair side time in minutes per visit for each of the three brackets under test

Bracket	N	Mean	SD	Min	Max
Damon 3MX	30	21.42	4.99	13.61	34.57
In-Ovation R	31	23.89	5.99	15.19	35.68
OMNI	16	24.59	5.94	15.98	34.96

Table 11 Summary data of chair side time per visit for patients who had completed treatment

The Kruskal Wallis non-parametric one way analysis of variance showed there to be no statistically significant difference in the chair side time per visit for each of the three brackets under test ($p=0.154$) even though the overall treatment time was longer in the case of the Omni bracket.

5.7.3 The overall treatment time in days

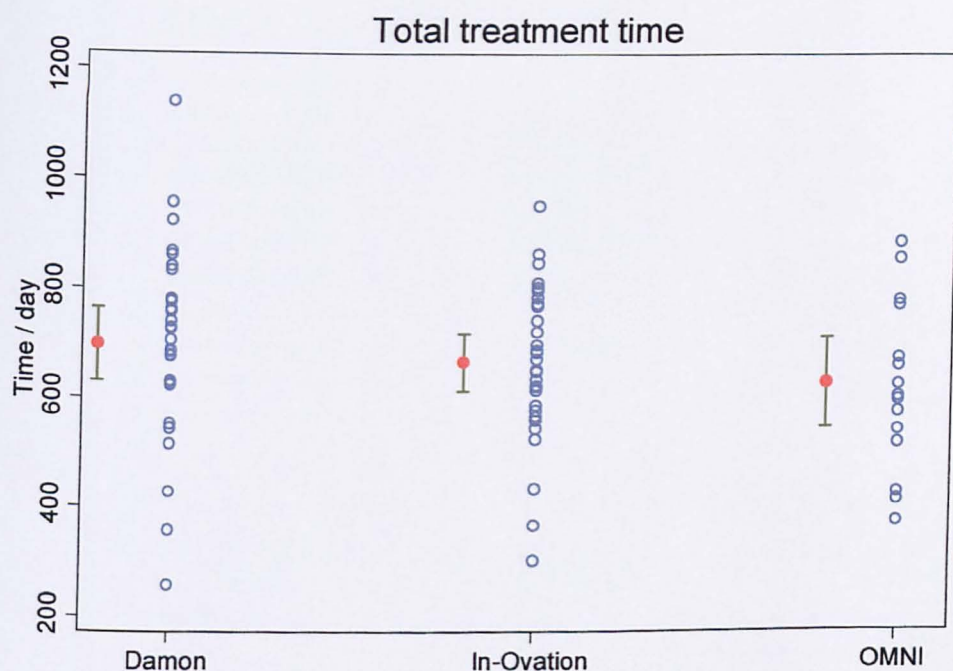


Figure 31 Means, 95% confidence intervals of the mean and raw data for total time in days for each of the three brackets under test

Bracket	N	Mean	SD	Min	Max
Damon 3MX	30	698.27	179.65	256.00	1141.00
In-Ovation R	31	667.10	144.89	302.00	951.00
OMNI	16	627.63	154.41	372.00	883.00

Table 12 Summary data of total treatment time in days

The Kruskal Wallis non-parametric one way analysis of variance showed there to be no statistically significant difference in the total overall treatment time in days for each of the three brackets under test ($p=0.318$)

5.7.4 The total number of appointments to debond

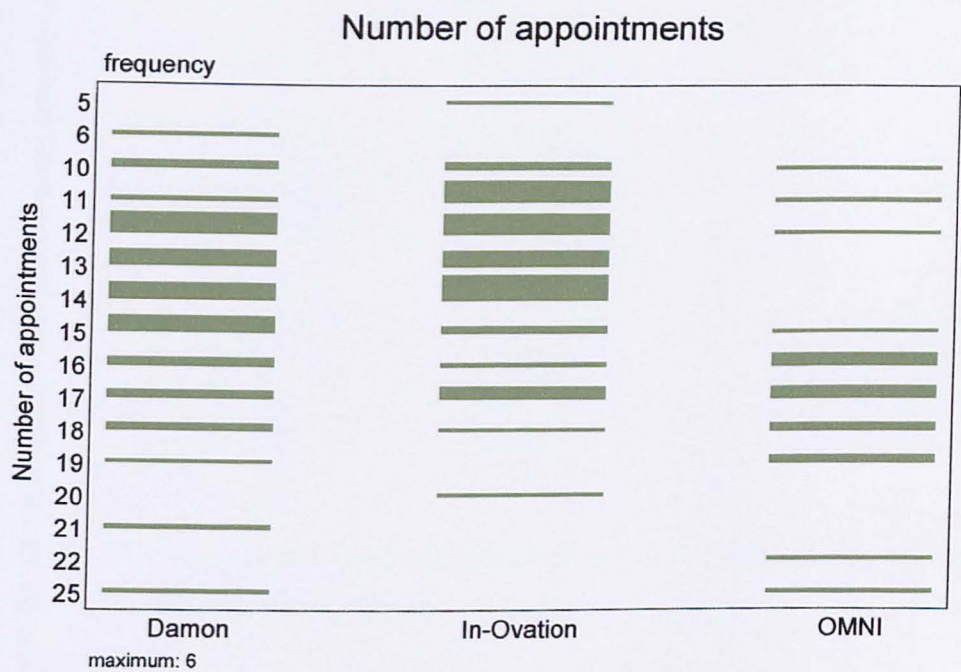


Figure 32 Frequency distribution plots for the number of appointments for each of the three brackets under test

The Kruskal Wallis non-parametric one way analysis of variance demonstrated a statistically significant difference between the groups ($p=0.007$) with an adjusted p value of 0.008. Further analysis using the Mann-Whitney test demonstrated no significant difference between the Damon 3MX and In-Ovation R brackets ($p=0.106$). There was also no statistically significant difference between the Damon 3MX and the Omni brackets ($p=0.019$), but there was between the In-Ovation R and the Omni brackets ($p=0.0009$).

5.7.5 The total number of emergency appointments

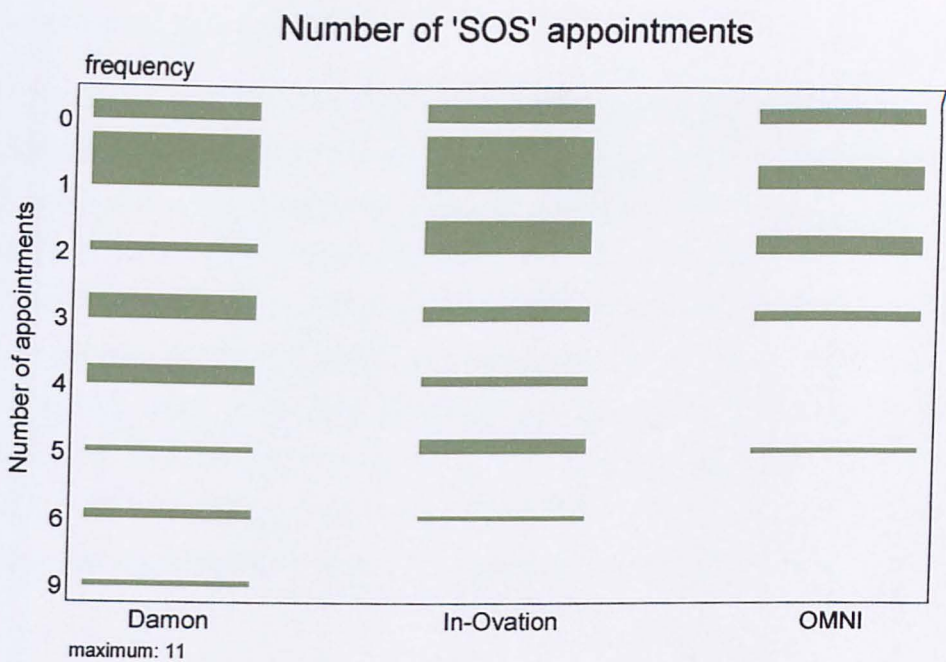


Figure 33 Frequency distribution plots for the number of emergency appointments for each of the three brackets under test

When the total number of unplanned emergency appointments were considered the Kruskal Wallis non-parametric one way analysis of variance demonstrated no statistically significant difference between the three brackets under test ($p=0.6$).

6 Discussion

6.1 Extraction vs. Non-Extraction

As part of the inclusion criteria of this investigation, all of the subjects required a loss of a premolar unit in each quadrant. This allowed all the subjects within each bracket group to be closely matched to ensure consistency. This is in contrast to a number of previous studies investigating similar variables. Harradine (2001) only had 40% of extraction cases in his study, Miles (2005) only 14% and Miles *et al.* (2006) 20%. These different rates of extraction may have influenced the rate of alignment and therefore their results should be interpreted with this in mind. Other researchers have carried out alignment studies on arches that were treated on a non-extraction basis (Pandis *et al.* 2007; Fleming *et al.* 2009; Pandis *et al.* 2010). The use of a non-extraction treatment plan may also have influenced the rate of alignment. Therefore their results cannot be used in direct comparison with this investigation.

6.2 Exclusions

There were three subjects within the current investigation who failed to complete treatment. One subject withdrew from the study, another moved away and the final subject had their treatment plan altered during treatment which meant that it did not match the investigation protocol. All of the subjects' results were still included within the data analysis as it was felt that their inclusion until their removal from the study would help with the power of the final results. The inclusion of their results was possible by the use of the linear mixed models, as using this analysis instead of conventional ANOVA allowed the inclusion of subjects with missing data.

6.3 Practical Clinical Issues

A number of clinical difficulties were encountered during this investigation. Due to the large numbers of participants in this study, it was not possible for all of the subjects to be treated by the same individual. This may have lead to differences in treatment times for certain clinicians. However, the clinicians involved in the investigation were not familiar with either

the passive or active SL brackets, and therefore they all experienced a similar learning curve which ensured that treatment times were comparable.

It was discovered that subjects who had undergone the extraction of the second premolars, sometimes had to have their initial aligning archwires (0.014" and 0.018") annealed and cinched distal to the molar bands. This was carried out to reduce the risk of these archwires dislodging from the molar bands. This risk could have been reduced by the placement of lacebacks. However, as lacebacks were prohibited as part of the treatment protocol, this was not an option. In certain situations, where the archwires repeatedly shifted, it was agreed that these archwires could be cut distal to the first premolar brackets.

It was felt that the transition from 0.018" CuNiTi to a 0.016" x 0.022" Stainless Steel was sometimes difficult to carry out. This was especially the case for the passive SL brackets (Damon 3MX). This was due to the inadequate derotation of the teeth with the 0.018" archwire, especially in the canine region. Therefore, it was necessary to sometimes place an elastomeric module over the SL bracket and archwire. This would then allow the closure of the passive slide at the next appointment. This problem may have been overcome by the use of an intermediate rectangular NiTi archwire, as recommended by the manufacturers of the self-ligating brackets, which could have enabled the bracket slot to be better filled, allowing for quicker alignment. However, this was not possible in this study as all subjects were treated using an identical archwire sequence.

6.4 Archwire Sequence

All of the manufacturers of the SL brackets advise on using a specific archwire sequence as part of their system. The manufacturers of the active SL bracket recommend the following archwire sequence:

0.014" CuNiTi

0.018" CuNiTi

0.020" x 0.020" CuNiTi

0.019" x 0.025" Stainless Steel

The square archwire is used to complete the alignment phase, as it is felt that the Cobalt-Chromium clip of the active SL bracket becomes interactive and uses the archwire to fully align the teeth.

The manufacturers of the passive SL bracket recommend a completely different archwire sequence as part of their treatment system. They advise the following archwire sequence:

0.014" CuNiTi

0.014" x 0.025" CuNiTi

0.018" x 0.025" CuNiTi

0.019" x 0.025" Stainless Steel

The use of the rectangular CuNiTi archwire is advocated because it is felt that the archwire can fill the slot and allow the bracket to derotate the teeth.

To make this investigation uniform and consistent, a standard archwire sequence was used. This was based on the orthodontic department's standard archwire sequence for the conventional brackets. It could be argued that the different SL brackets could have performed better if their respective archwire sequences were used.

6.5 Frankfort Mandibular Planes Angle

It has been reported in the literature that space closure is more difficult in subjects with a low FMPA ($< 22^\circ$) due to higher muscular forces (Moller 1966). Conversely, it is also widely thought that space closure or tooth movement is quicker in subjects with a high FMPA ($> 32^\circ$), although there is no evidence to support this. This study found that there was no statistically significant difference in the distribution of FMPA with either gender ($p=0.44$) or bracket type ($p=0.99$). It also found that there was no significant effect of FMPA on space closure.

6.6 Bracket Prescription

A number of studies investigating the rate of initial alignment and space closure have not mentioned whether the different brackets under investigation had similar bracket prescriptions (Miles *et al.* 2006; Burrow 2010; Ong *et al.* 2010). The study by Scott *et al.* (2008) highlighted the use of differing prescriptions as a potential criticism of their study.

Graber *et al.* (2005) have speculated that active SL brackets can express their torque from an earlier treatment stage due to the active spring clip pushing the archwire into the base of the slot. Badawi *et al.* (2008) have shown that the active clip did influence 3rd order tooth position by reducing the 'slop' within the slot by 7 degrees. To avoid this problem and to have true equivalence, this investigation used the same bracket prescription for all three bracket types. Although, it has to be noted that the final archwire in our sequence was a 0.019" x 0.025" Stainless Steel and therefore the full torque values may not have been fully expressed.

6.7 Pre-treatment crowding

Shivapuja and Berger (1994) have suggested that pre-treatment initial malalignment is an important factor when determining the rate of initial alignment. It is therefore logical to assume that the greater the initial malalignment, the faster the rate of alignment, as the archwires will be more efficient when ligated to grossly displaced teeth.

Pandis *et al.* (2007) found that there was a statistically significant difference in alignment for patients with moderate crowding <5 mm. They showed that the SL bracket group completed alignment 2.7 times faster than the conventional bracket group. A similar but less powerful tendency was shown with severe crowding, as alignment was 1.37 times faster with the SL bracket compared to the conventional bracket, but this was not significant. These results may be due to the fact that they used an initial 0.016" NiTi and then 0.020" Sentalloy for the conventional bracket group and an initial 0.014" NiTi and followed by a 0.014" x 0.025" NiTi for the SL bracket group.

This investigation showed no statistically significant difference in the pre-treatment Little's Index of Irregularity for all of the three bracket groups ($p=0.234$). Therefore, pre-treatment

crowding was not an important factor in the initial alignment findings where alignment was fastest with the Omni bracket.

It has also been shown by Leighton and Hunter (1982) that patients with a larger FMPA were more likely to have increased crowding. However, this study showed no statistically significant difference in the distribution of FMPA and bracket group ($p=0.99$) and as there was no difference detected between pre-treatment crowding and bracket group ($p=0.234$), this suggests that there is no relationship between FMPA and crowding.

6.8 Measurement Period

Many studies investigating the rates of initial alignment and space closure using conventional and SL brackets have only recorded values at certain dates *i.e.* week 10 and week 20 (Miles 2005; Miles *et al.* 2006) and have not continued measurement until the end of treatment (Ong *et al.* 2010; Mezomo *et al.* 2011). These results need to be evaluated with caution as the changes observed may not have been comparable for the entire period of treatment. Also some changes between different bracket types may only become apparent after a longer period of time (Fleming *et al.* 2009). Pandis *et al.* (2007) have shown that the active clip in In-Ovation R brackets can relax during use and therefore could contribute to a lack of consistent engagement of the archwire throughout treatment. Therefore this investigation measured the changes in alignment and space closure of subjects in all three bracket types till the end of their treatment.

6.9 Effect of bracket on alignment

This investigation demonstrated a significant difference in the rate of initial alignment of the labial segments in relation to both the bracket type ($p=0.01$) and the jaw ($p=0.001$). It found that the initial alignment was faster with all three bracket types in the mandible ($p=0.026$) and that there was a significant difference between the conventional bracket and both the self-ligating brackets. These results are similar to the study by Miles *et al.* (2006) who also showed that there was a significant difference in alignment between conventional and passive SL brackets in the mandible. However, their study was flawed as it was only carried out for twenty weeks, it was a split mouth design which may have influenced the rate of alignment

and it was not clear whether the patients were extraction or non-extraction cases. The results of this study are in contrast to a number of other studies that show there is no difference between the rate of initial alignment between different bracket types (Scott *et al.* 2008; Fleming *et al.* 2009; Ong *et al.* 2010).

The faster rate of alignment in the mandible for all three brackets could be explained by the smaller inter-bracket distances between the lower labial teeth. This would cause the archwire to be in contact with more of the bracket over shorter distances and allow less deflection *i.e.* more active forces to align the teeth. The fact that there was no difference in the rate of alignment between either of the bracket groups, particularly the passive and active SL brackets in the maxilla confirms this. It is also in agreement with Pandis *et al.* (2010) who showed no difference in the alleviation of crowding between an active or passive SL bracket used in the maxilla.

In addition, the faster alignment with the use of the conventional bracket, when compared to both of the self-ligating brackets could be due to a number of other factors. The archwire, even if it is a 0.014" in the conventional bracket is ligated firmly into the base of the slot every time, ensuring good rotational control. The same archwire within a passive SL bracket is not positively pushed into the base of the slot and therefore has the ability to move freely within the 0.022" x 0.028" tube. The same argument can be made for the active SL bracket, as it has been shown that only archwires above a certain dimension, namely 0.018", will cause the clip to become interactive, and enable the resulting archwire to be pushed into the back of the slot, thus allowing further control in the first and second order positions of the teeth. These results differ to those previously published by a number of other researchers (Pandis *et al.* 2007; Scott *et al.* 2008; Fleming *et al.* 2009; Ong *et al.* 2010).

It has also been postulated that the differing widths of the brackets could have an effect on the rate of alignment. Narrower brackets generate higher moments which lead to higher forces at the edge of the bracket when compared to wider brackets (Drescher *et al.* 1989). These increased forces could increase the critical contact angle and lead to increased notching and binding (Ong *et al.* 2010), which can affect the resistance to sliding and hence the rate of alignment. This may be one of the explanations for the differing rates of initial alignment between the brackets under investigation in this study.

The frequent appointments and shorter intervals for the conventional bracket may also have allowed faster progression up the recommended archwire sequence, causing a faster rate of

alignment. It has been shown by Taloumis *et al.* (1997) that elastomeric modules undergo a rapid force loss within the first 24 hours and that they can also be affected by the oral environment. This is one of the main reasons that the conventional bracket group subjects were recalled every 6 weeks. This was in contrast to both of the SL bracket groups which were seen every 12 weeks. The appointment interval was a recommendation by the SL bracket manufacturers. This increase in appointment interval time whilst using SL brackets, may have had an effect on the rate of alignment. Even if the teeth had aligned fully and the specific archwire was passive after six weeks, the archwire would not be changed for another six weeks thus delaying the progression to the next archwire in the sequence.

An interesting finding of this investigation was that the majority of subjects with the passive SL bracket did not fully achieve a Little's Index of Irregularity of zero, even at the end of treatment. This was despite the placement of the final 0.019" x 0.025" Stainless Steel archwire. This can only be explained by the 'slop' of the SL brackets being larger than the other brackets under investigation, due to a larger dimension of the bracket slot (Bhalla *et al.* 2010) and therefore allowing minute movements of the labial teeth in the first order (Harradine 2003).

6.10 Effect of bracket on space closure

The different bracket types demonstrated a number of significant differences in relation to extraction space closure. The conventional bracket showed a significant interaction of both gender and jaw, whilst the passive SL bracket only showed a significant effect with jaw in females. This was in contrast to the active SL bracket which showed a significant interaction with gender but not with jaw.

Investigating this further, led to the discovery that extraction space closure was significantly faster in males for both the conventional ($p=0.003$) and active SL bracket groups ($p=0.001$) and whilst not being statistically significant for the passive SL group, space closure was still faster in males in comparison to females.

This interesting discovery was again confirmed by the student t-test carried out on all of the pooled data, which confirmed that space closure was faster in males than in females ($p=0.001$).

It has been recommended by a number of researchers that treatments, especially involving extractions, should be carried out during a period of maximal growth (Stephens & Houston 1985; Nanda & Nanda 1992). They have suggested that to obtain maximum space closure, both males and females should be treated during their pubertal growth spurt. Tanner *et al.* (1976) has shown that on average males have their pubertal growth spurt at 14 years \pm 2 years, whereas females have their pubertal growth spurt at 12 years \pm 2 years. Considering the sample in this investigation, it showed the mean age of the male and female subjects to be 14.21 years and 13.96 years respectively. This could explain the faster rate of space closure in males as they were treated during their pubertal growth spurt, whereas the females still experienced space closure but at a slower rate as they had already undergone much their pubertal growth spurt. To our knowledge this is the first time a positive relationship between sex and rate of tooth movement has been demonstrated so conclusively in a clinical trial. Previous workers have merely suggested this might be the case based on anecdotal evidence.

Another consistent finding with all three bracket types was a reversal in the rate of space closure during treatment as illustrated in the cubic spline plots (Figures 26 to 28). An explanation for this change could be the difference between passive extraction space closure phase and active extraction space closure phase. Ong *et al.* (2010) showed passive extraction space closure can occur during the initial alignment phase of treatment. This could explain the initial faster rate of space closure observed in this study. However, once the arches have been aligned and levelled which is shown by a lag phase, then active extraction space closure can commence. The application of an active force to allow sliding mechanics can then facilitate further space closure, which was represented by the second increased rate of space closure. The interim transition period between completing the initial alignment phase and prior to commencing the active space closing phase may explain the change in the rate of extraction space closure for all three bracket types.

6.11 Treatment times

The efficiency of treatment with the different bracket types was also investigated and once again showed some significant differences.

There was a significant difference in total chair side time between the conventional bracket and both of the SL brackets ($p=0.013$). The conventional bracket group took an average of 50

minutes longer than both the passive and active SL bracket groups. There was also a significant difference in the total number of appointments to debond between the conventional group and the active SL group ($p=0.0009$). Both of these results can be explained by the shorter six week interval between appointments for the conventional bracket group. The SL bracket group subjects were only recalled every 12 weeks. This meant that the majority of the conventional group subjects had double the number of appointments when compared to their fellow counterparts in both the SL bracket groups over the same time period. Both of these results are contrary to the conclusions reached by Hamilton *et al.* (2008), who found in their retrospective study that there was no measurable difference between active SL brackets and conventional brackets when investigating the number of visits.

The conventional Omni bracket is priced at £3.05, the Damon 3MX is £11.12 and the In-Ovation R is £9.75 (Personal Communication). It has been suggested that the increased cost of these SL brackets could be offset by the reduction in chair side time (Majjer & Smith 1990; Berger & Byloff 2001), which would allow more patients to be seen and treated. Turnbull and Birnie (2007) have also shown a small financial saving related to elastomeric modules not being required. However, as Fleming *et al.* (2009) discussed, it remains unclear whether the time and money saved in terms of number of appointments and reduced chair side time justify the extra cost.

This study has shown that there was no significant difference in the mean chair side time *i.e.* appointment time at each individual visit between either bracket group when the subjects were seen for appointments ($p=0.154$). This is in contrast to Shivapuja and Berger (1994) who found a dramatically shorter chair side time for the removal and insertion of the archwires in SL brackets when compared to conventional brackets. This was again the case with Turnbull and Birnie (2007), who found a significant difference between the time taken for the placement and removal of archwires using a passive SL and a conventional bracket, with the passive being quicker. This tendency was not observed in this study as the whole treatment appointment was timed rather than just the untying and ligation of the archwires.

This investigation also found there was no difference in the total overall treatment time in days ($p=0.318$). This is similar to results published by DiBiase *et al.* (2011) who compared the duration of treatment using a passive SL bracket with a conventional bracket group and found no overall reduction in treatment time.

Finally, it was shown that there was no statistically significant difference between all three bracket types when considering the total number of unplanned emergency appointments ($p=0.6$). This is in contrast to studies carried out by Miles *et al.* (2006) and Hamilton *et al.* (2008), which both showed significantly higher breakages associated with the SL brackets and which they attributed to the bracket profile. Both, Damon 3MX and the In-Ovation R brackets are larger inciso-gingivally and labio-lingually when compared to the conventional Omni bracket and in addition they both have a smaller bonding base. These factors could have increased the likelihood of these brackets interfering with the occlusion and leading to bracket bonding failures (Chen *et al.* 2010). However, it is worthwhile noting that the study by Hamilton *et al.* (2008) was retrospective and that the patients were not treated using a similar archwire sequence. While the study by Miles *et al.* (2006) only reported first time failures for each tooth and no other subsequent failures. The results from this current investigation confirm the findings reported by a number of other researchers who also found no difference between conventional and SL brackets (Pandis *et al.* 2006; Chen *et al.* 2010; DiBiase *et al.* 2011).

Proponents of the SL brackets, especially the passive Damon 3MX may well disagree with the majority of the results in this investigation. This is because, it could be argued that the full benefits of these brackets were not expressed. The subjects in this study were not treated using the Damon philosophy, *i.e.* a low friction system to achieve physiologic adaptation, by allowing light forces to align crowded arches without the need of extractions. Or in other words the Damon archwire sequence on a non-extraction basis. In answer to this, firstly all of the subjects included in this study presented with sufficient crowding in both arches, to necessitate extractions. In any case Pandis *et al.* (2007) have shown that patients with severe crowding showed no difference in the rate of alignment with the Damon SL bracket. Secondly, the use of anchorage reinforcement for some subjects could also have hindered the SL brackets from demonstrating their advantages. However, it is important to reiterate that this study was carried out to investigate the brackets and not the archwire system or extraction/ non-extraction philosophies. Therefore it was appropriate to carry out accepted treatment plans that would be generally advised for all of the subjects presenting for treatment at any other time.

Although all of the results regarding space closure and treatment times are very interesting and show a number of significant differences, it has to be remembered that at the time of data analysis the final twenty three subjects were still undergoing treatment, notably space closure

and had not completed the full trial. It is envisaged that their results will eventually be incorporated into the existing study and further strengthen the power of the results.

7 Conclusions

The following conclusions can be drawn from this investigation:

1. There was a statistically significant difference in the rate of initial alignment with the use of OMNI conventional brackets when compared to the Damon 3MX passive and In-Ovation R active self-ligating brackets. The conventional brackets aligned the labial segment teeth quicker.
2. There was a statistically significant difference in the rate of initial alignment in the mandible with the use of all three bracket types when compared to the maxilla. All three bracket types aligned the mandibular labial segment quicker than the maxillary labial segment.
3. There was a statistically significant difference in the rate of space closure in the buccal segments in males with OMNI conventional brackets and In-Ovation R active self-ligating brackets. Although not statistically significant, the rate of buccal space closure was also faster in males with Damon 3MX passive brackets.
4. There was a statistically significant difference in the total chair side time between the OMNI conventional brackets and both the Damon 3MX passive and In-Ovation R active self-ligating brackets. The conventional bracket group took an average of fifty minutes longer to complete treatment which is explained by the shorter appointment intervals with the Omni brackets.
5. There was a statistically significant difference in the total number of appointments between the OMNI conventional bracket and the In-Ovation R active self-ligating bracket. The conventional bracket group took more appointments to complete treatment which is again explained by the shorter appointment intervals with the Omni brackets.
6. The rate of space closure was greater in males than females, which appears to be related to the time of the pubertal growth spurt.

8 Future Work

As stated earlier, this clinical trial still has a number of patients undergoing final buccal segment space closure. These remaining subjects within the study will be followed up until the end of their treatment and the data reanalysed in order to confirm these interim findings. This will further improve the power of the trial.

The following also merit further investigation:

1. A repeat of the study using the manufacturers' recommended archwire sequences for each bracket type to see if this has any additional effect on the rate of initial alignment and space closure.
2. A repeat of the study with subjects treated on a non-extraction basis in order to establish if the results observed are similar to the present investigation.
3. A repeat of the study with the inclusion of other popular self-ligating brackets in order to discern any differences in the rate of initial alignment or extraction space closure with different bracket designs.

9 References

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Appendix 1

Department of Orthodontics

Taunton and Somerset Hospital

Musgrove Park

TAUNTON

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Telephone: 01823 344702

Facsimile: 01823 342169

Information Sheets for Participants (Child)

Study title: Comparing 3 types of metal orthodontic brackets

We are asking if you would agree to take part in a research project to find the answer to the question:
'Is treatment quicker with self-clipping orthodontic brackets?'

Before you decide if you want to join in it's important to understand why the research is being done and what it will involve for you. So please read this leaflet carefully and talk about it with your family, friends, dentist if you want to. Ask us if there is anything you do not understand or if you would like more information.

Thank you for reading this.

Why are we doing this research?

Some orthodontic metal braces do not need coloured elastic rings to hold the wires in place they have a clip instead. Some people think that these braces are faster and need fewer appointments to complete orthodontic treatment. We do not know for sure this is the case. This study aims to look at whether one type of fixed-on orthodontic brace is faster than another.

What is the device or procedure that is being tested?

We are looking at 3 different types of metal orthodontic brackets.

Why have I been asked to take part?

Approximately 100 people will be invited to join the study and they are all patients who are about to start orthodontic treatment (fixed-on braces) in the hospital at the moment.

Do I have to take part?

No! It is up to you, taking part is entirely voluntary. If you do not wish to take part then you do not have to. You will not have to give a reason why and it will not affect your treatment if you don't.

What will happen to me if I take part?

Your orthodontist will ask you to sign a form giving your consent. You will be given a copy of this information sheet and your signed form to keep.

You are free to stop taking part at any time during the research without giving a reason. If you decide to stop, this will not affect the care you receive.

What will I be asked to do?

You will have one of 3 types of orthodontic metal brackets (fixed-on brace) placed at the start of your treatment. This choice of bracket will be made randomly by the Hospital and not by your orthodontist. You will need to have dental impressions (moulds of your teeth) taken every 12 weeks during treatment. These impressions will be taken at your routine orthodontic appointment and you will not be asked to attend for any extra visits.

What are the side effects of the types of appliances?

The side effects are only those that we would expect as part of routine orthodontic treatment and will be explained to you as part of the normal consent to treatment process.

Is there anything else to be worried about if I take part?

There is nothing to worry about. The only difference with taking part in the study is that extra sets of dental impressions (moulds of your teeth) will be taken every 12 weeks at your routine appointments.

What are the possible benefits of taking part?

Two of the types of orthodontic brackets (braces) are reported to give quicker treatment times and need fewer appointments.

What happens if new information about the research appliance comes along?

The appliances to be used in the present study have been in routine use for about 5 years and, hence, no new information is expected to arise that will affect your treatment.

What if there is a problem or something goes wrong?

If the brace breaks during treatment then you should contact the Orthodontic Department on 01823 342175 and will be advised on what to do. This is the same whether you were or were not taking part in the study.

Will anyone else know I'm doing this?

It is normal for research inspectors to look at research medical files to make sure the research is being done properly. If you agree to take part in the research, any of your medical records may be looked at to check that the study is being carried out correctly. Your name, however, will not be disclosed outside the hospital. Your dentist will be told as a matter of routine that you are undergoing orthodontic treatment but not that you are taking part in the study unless you give permission.

All information that is collected about you during the course of the research will be kept strictly confidential.

What will happen to the dental moulds taken for this study?

These moulds will be measured as part of the research study. They will be kept in a locked room when stored.

After your treatment is finished all the moulds of your mouth will be kept for 9 years before being destroyed. This is a legal requirement.

All information which is collected about you during the course of the research will be kept strictly confidential.

Who is organising and funding the research?

Miss N E Attack, Consultant Orthodontist will be organising the research.

Neither your orthodontist nor the hospital department will be paid for including you in this study.

Who has reviewed the study?

Before any research goes ahead it has to be checked by an Ethics Committee. They make sure that the research is OK to do. Your project has been checked by the Somerset Research Ethics Committee and an external reviewer.

Thank you for reading this – please ask any questions if you need to.

Contact Details:

For further information you can contact Nikki Attack or Nick Mitchell, Orthodontic Department, Taunton and Somerset NHS Trust, Musgrove Park, Taunton, TA1 5DA

Telephone Number: 01823 344702

e-mail: nikki.atack@bristol.ac.uk or nick.mitchell@tst.nhs.uk

Thank you for reading

Taunton and Somerset 
NHS Trust

Information sheets for parents/guardians

Study title: Comparing 3 types of metal orthodontic brackets

We are asking your child if they would agree to take part in a research project to find the answer to the question: *'Is treatment quicker with self-clipping orthodontic brackets?'*

Before they decide it's important to understand why the research is being done and what it will involve for them. This leaflet will give you information regarding the study. Ask us if there is anything you do not understand or if you would like more information.

Thank you for reading this.

What is the purpose of the research project?

Some orthodontic metal braces do not need coloured elastic rings to hold the wires in place they have a clip instead. Some people think that these braces are faster and need fewer appointments to complete orthodontic treatment. We do not know for sure this is the case. This study aims to look at whether one type of fixed-on orthodontic brace is faster than another.

Why has my child been chosen?

Approximately 100 people will be invited to join the study and they are all patients who are about to start orthodontic treatment (fixed-on braces) in the hospital at the moment.

Does my child have to take part?

No! It is up to you and your child, taking part is entirely voluntary. If you do not wish to take part then you do not have to. You will not have to give a reason why and it will not affect your treatment if you don't.

You are both free to withdraw from the research at any time and without giving a reason. Your decisions about this will not affect the standard of care your child will receive.

What will happen to my child if we agree to take part?

Your orthodontist will ask you to sign a form giving your consent. You will be given a copy of this information sheet and your signed form to keep.

You are free to stop taking part at any time during the research without giving a reason. If you decide to stop, this will not affect the care you receive.

What does my child have to do if we agree to take part?

They will have one of 3 types of orthodontic metal brackets (fixed-on brace) placed at the start of their treatment. This choice of bracket will be made randomly by the hospital and not by the orthodontist.

They will need to have dental impressions (moulds of their teeth) taken every 12 weeks during treatment. These impressions will be taken at their routine orthodontic appointment and you will not have to attend for any extra visits.

What is the appliance (Orthodontic fixed-on brace) that is being tested?

3 different types of orthodontic fixed-on braces are being investigated: 2 have clips to hold the wire in place and one uses elastic bands.

What are the alternatives for treatment?

Your child will require fixed-on braces to straighten their teeth. If you do not wish to participate in the study the conventional brackets with elastic bands will be used.

What are the side effects of any treatment received when taking part?

The side effects are only those that we would expect as part of routine orthodontic treatment and will be explained to you and your child as part of the normal consent to treatment process.

What are the other possible disadvantages of taking part?

Compared with not taking part in the study, the only difference with taking part is that extra sets of dental impressions (moulds of your child's teeth) will need to be taken every 12 weeks at the routine appointments.

What are the possible benefits of taking part?

Two of the types of orthodontic brackets (braces) are reported to give quicker treatment times.

What if there is a problem?

If the brace breaks during treatment then you should contact the Orthodontic Department on 01823 342175 and will be advised on what to do. This is the same whether or not your child was taking part in the study.

Will my child's taking part in the research project be kept confidential?

It is normal for research inspectors to look at your child's research medical files to make sure the research is being done properly. If you agree to take part in the research, any of your child's medical records may be looked at to check that the study is being carried out correctly. Their name, however, will not be disclosed outside the hospital.

Your dentist will be told as a matter of routine that your child is undergoing orthodontic treatment but not that your child is taking part in the study unless they have agreed and consented for this to happen.

All information that is collected about your child during the course of the research will be kept strictly confidential.

What if relevant new information becomes available?

The appliances to be used in the present study have been in routine use for about 5 years and, hence, no new information is expected to arise that will affect the treatment.

What will happen if my child or I don't want to carry on with the research?

Your child is free to stop taking part at any time during the research without giving a reason. If you or they decide to stop, this will not affect the care they receive.

Involvement of the Dentist?

Your dentist will be told as a matter of routine that your child is undergoing orthodontic treatment but not, as a matter of course, that they are taking part in the study. The dentist will be informed that your child is taking part in the study if they agree to this.

What will happen to the dental moulds my child gives?

These moulds will be measured as part of the research study. They will be kept in a locked room when stored.

After their treatment is finished all the moulds of their mouth will be kept for 9 years before being destroyed. This is a legal requirement.

All information which is collected about your child during the course of the research will be kept strictly confidential.

What will happen to the results of the research study?

The results will be presented at Dental Conferences and published in orthodontic journals but all the patients will remain anonymous.

Who is organising and funding the research?

Miss N E Attack, Consultant Orthodontist will be organising the research.

Neither your orthodontist nor the hospital department will be paid for including you in this study.

Who has reviewed the study?

Before any research goes ahead it has to be checked by an Ethics Committee. They make sure that the research is OK to do. Your project has been checked by the Somerset Research Ethics Committee and an external reviewer.

Thank you for reading this – please ask any questions if you need to.


Contact Details:

For further information you can contact Nikki Atack or Nick Mitchell, Orthodontic Department, Taunton and Somerset NHS Trust, Musgrove Park, Taunton, TA1 5DA

Telephone Number: 01823 344702

e-mail: nikki.atack@bristol.ac.uk or nick.mitchell@tst.nhs.uk

Thank you for reading

Taunton and Somerset 
NHS Trust

Centre Name: Orthodontic Dept, Taunton and Somerset, NHS Trust

Study Number:

Patient Identification Number for this trial:

CONSENT FORM

Title of Project: Comparing 3 types of orthodontic metal brackets

Name of Researcher: Miss N E Attack

Please initial box

1. I confirm that I have read and understand the information sheet dated 16/01/2006 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that relevant sections of any of my medical notes and data collected during the study, may be looked at by responsible individuals from the NHS Trust where it is relevant to my taking part in this research. ☐
 I give permission for these individuals to have access to my records.
4. I give permission for my dentist to be informed that I am involved in this research. ☐
5. I agree to taking part in the above study. ☐

 Name of Patient

 Date

 Signature (Child)

 Name of Parent/Guardian

 Date

 Signature (Parent/Guardian)

 Name of Person taking consent
 (if different from researcher)

 Date

 Signature

 Researcher

 Date

 Signature

When completed; 1 for patient; 1 for researcher site file; 1 (original) to be kept in medical notes